VOLUME 9 NUMBER 3

Food-Drug-Cosmetic Law Journal

MARCH • 1954

The Society of Public Analysts and Other Analytical Chemists . . . . . GEORGE TAYLOR

Enforcement and Judicial Progress in 1953 . . . . . WILLIAM W. GOODRICH

Druggist, Beware! Absolute Criminal Liability Is Here . . RICHARD C. NELSON

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A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $10 per year, including a handsome binder to hold one year's issues. Single copies are $1 each. Editorial and business offices, 214 N. Michigan Ave., Chicago 1, Ill. Printed in United States of America.

March, 1954
Volume 9 • Number 3

Entered as second-class matter December 30, 1948, at the Post Office at Chicago, Illinois, under the Act of March 3, 1879.

FOOD DRUG COSMETIC LAW JOURNAL

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FOOD DRUG COSMETIC LAW JOURNAL

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About the Authors

George Taylor, president of Great Britain's Society of Public Analysts and Other Analytical Chemists from 1948 to 1950, was trained at Finsbury Technical and Kings Colleges. In 1900, he joined the staff of Dr. Bernard Dyer, public analyst for the County of Essex.

Seventeen years later, he qualified as a fellow of the Royal Institute of Chemistry, and was subsequently appointed joint public analyst for Essex and other counties and borough councils.

In 1948, Mr. Taylor was decorated by King George VI as an officer of the Most Excellent Order of the British Empire. A member of the food-standards committee of the Ministry of Food since 1941, Mr. Taylor has—for the past two years—also been associated with the Ministry of Agriculture, as a member of the advisory committee, Fertilisers and Feeding Stuffs Act.

William W. Goodrich presents in this issue his annual summary of enforcement and judicial progress at the federal level. JOURNAL readers will recall Mr. Goodrich's article on simplifying the trial of scientific issues in formal rule-making under the Act which appeared in last September's JOURNAL. He is assistant general counsel in the Department of Health, Education, and Welfare.

A 1952-1953 fellow in the New York University program of graduate food and drug law instruction, **Richard C. Nelson** at present is the Assistant United States Attorney administering the Federal Food, Drug, and Cosmetic Act for the Northern District of California. He holds degrees in law from Stanford and New York Universities.

Reprinted from *Food Technology* is an article on insecticide residues in food products. Writers of the article are **W. E. Baier** and **C. W. Wilson,** of the research department, California Fruit Growers Exchange, Ontario, California. Mr. Baier is manager of that department.

Roy S. Pruitt has served as Chief of St. Louis District, Food and Drug Administration, since 1943. A 1929 graduate of the University of Arkansas, with a degree in chemistry, he entered FDA the same year as analyst, serving at St. Louis, New Orleans and Washington, and as chief chemist at Cincinnati Station, where he was appointed Chief in 1942.

Thomas W. Christopher notes recent judicial, administrative and legislative developments in his "Significant Comments," which round out this March JOURNAL. Mr. Christopher is an associate professor of law at Emory University.

In the Food and Drug Administration

Monthly Report Issued February 25, 1954.—Fifty-six shipments of foods and 17 of drugs and devices were seized in January on charges that they violated the Federal Food, Drug, and Cosmetic Act, according to a report released by the Food and Drug Administration, United States Department of Health, Education, and Welfare.

Of the 304,331 pounds of unfit food seized, 217,932 pounds became contaminated with filth or decomposed while in storage after interstate shipment. A large portion consisted of flour and cereals stored without adequate protection from rodents.

Nine of the drugs and devices seized were labeled with misleading therapeutic claims, and three others failed to give adequate directions for use. The labeling on these three gave no indication of the purpose of the preparations. Five shipments of drugs and devices were seized because of faulty composition or contamination.

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Food·Drug·Cosmetic Law
Journal

The Society of Public Analysts and Other Analytical Chemists

By GEORGE TAYLOR

A Former President of the Society Outlines the History and Significance of this British Organization, and the Contribution of the Public Analyst in the Field of Food Legislation and Its Administration

Foreword

Because my society originated as an association of public analysts named the "Society of Public Analysts" and, in due course, became generally known and accepted by the initials "S. P. A.," it happened that when it was deemed desirable in later years to alter the name to the "Society of Public Analysts and Other Analytical Chemists," in order to recognize the newer and rapidly increasing membership of analytical chemists other than public analysts, the original name continued to be generally used. It therefore further happened that to many English chemists, lawyers, administrators of local government, and industrialists not in close touch with the society and its developments, the scope, purpose and activities of the society were misunderstood to be concerned only with public analysts. This position persists here to the present day.

I think that it is not only probable but nearly certain that, generally speaking, lawyers and chemists in America who are interested in food law and who know of my society are also under this misappre-

hension. It is my hope that this short article dealing with the history of the birth and development of the society, the basic contribution of public analysts, and the present-day position in respect of public analysts will serve to clear the fog of misunderstanding. I would like to add that in England we have the greatest admiration for the work of the Association of Official Agricultural Chemists, which we know affectionately as the A. O. A. C., and which we recognize as being as appropriately named as our own S. P. A.

Much of the historical matter has been taken from Bernard Dyer's reminiscences of the first 50 years of the society.[1]

Society of Public Analysts and Other Analytical Chemists

In England, in the early nineteenth century, the question of food adulteration appears to have become sufficiently acute for public interest to have been aroused and stimulated by the publication of a number of books dealing with the matter in a distinctly sensational fashion. Probably the first of these works was *Poison Detected or Frightening Truths* by "My Friend a Physician." In this book the practices of treating tea with copperas, beer with vitriol, and bread with alum, chalk and even powdered bones were condemned. In 1820 Frederick Accum published *A Treatise on Adulteration of Food and Culinary Poisons,* and this had, as a frontispiece, a picture of a pot with the inscription: "There is Death in the Pot, 2, Kings, C. IV, V, 40." About the same time there appeared *Wine and Spirit Adulterators Unmasked* by "One of the Old School." In his presidential address to the society in 1927, E. R. Bolton, referring to early adulteration and Accum's "Death in the Pot" quoted the following review of the book in Blackwood's *Edinburgh Magazine:*

> So inextricably are we all immersed in the mighty labyrinth of fraud that even the vendors of poison themselves are forced by a sort of retributive justice to swallow in their turn. Thus the apothecary, who sells the poisonous ingredients to the brewer, chuckles over his roguery and swallows his own drugs in his daily copious exhibitions of brown stout. The brewer, in his turn, is poisoned by the baker, the wine merchant, and the grocer. And, whenever the baker's stomach fails him, he meets his coup de grace in the adulterated drugs of his friend the apothecary, whose health he has been gradually contributing to undermine by feeding him every morning on chalk and alum in the shape of hot rolls.

In 1850 Wakley, the then editor of the *Lancet,* set up the "*Lancet* Analytical Sanitary Commission" to investigate the question of food

[1] *The Society of Public Analysts and Other Analytical Chemists* (W. Heffer, Cambridge): Dyer, "Some Reminiscences of Its First Fifty Years"; and Mitchell, "A Review of Its Activities."

adulteration in London and its neighborhood. This commission, in the charge of Dr. Hassall, pursued its investigations—often resulting in more or less startling revelations—until 1857 when the matter of its various reports were published in a collective volume. The suggestion of analytical competency in the name of this commission when first set up must have been somewhat optimistic because in 1851 Sir Charles Wood, chancellor of the Exchequer, stated in the House of Commons that in the opinion of three of the most distinguished chemists of the day "neither by chemistry nor by any other means could the admixture of chicory with coffee be detected." [2] In these circumstances a Treasury minute allowed the unrestricted mixture of chicory with coffee. Import duty was paid on both. But by 1853 Hassall's microscopic work was such that a further Treasury minute prescribed the labeling of coffee and chicory mixture in letters at least one eighth of an inch in height. Publication in the *Lancet* of 2,000 to 3,000 names of fraudulent traders caused a commotion, but only one legal proceeding against the *Lancet* was started, and this was ultimately dropped. Hassall's book, *Food and its Adulteration,* was published in 1855.

It was in consequence of the publication of the investigations by the *Lancet* commission that, in 1855, a select parliamentary committee was appointed which, after taking much evidence, issued a report which resulted in the passing of the first adulteration act in 1860 under the title "Adulteration of Food and Drink Act." This act proved in practice to be little more than a dead letter, but it must be regarded as noteworthy from our point of view because it permitted the appointment of analysts in the counties by courts of quarter sessions, while the same privilege was conferred on the commissioners of sewers in the City of London, and on the vestries and district boards of the metropolis generally. But such appointment of analysts was not compulsory.

In this connection I note with great interest that R. E. Curran, legal adviser to the Canadian Department of National Health and Welfare, in his article in 1951 on "British Food and Drug Law—A History" [3] states that modern legislation owes a great deal to this act and that, in introducing the official analyst, it introduced a "steadfast and dependable companion through the succeeding evolutionary years." I think I would go further than this and would say that 1860

[2] Monier-Williams, "Historical Aspects of the Pure Food Law," *Proceedings of the Nutrition Society* (March 3, 1951).

[3] 6 FOOD DRUG COSMETIC LAW JOURNAL 247-258 (1951).

marks not only the birth of the food analyst, but also the birth of food analysis. It was an era of food adulteration. The cry from the people for protection could not be ignored. Parliament moved, and a law against adulteration of food was brought into force. But this was of necessity, in the absence of any working science of analytical chemistry, an act designed by lawyers to enforce a line of action, deviations from which could only be detected by the aid of a science then more or less nonexistent.

It was therefore inevitable that the law must fail. But it was a spur and challenge to the scientist, and one of the men who accepted the challenge was Hassall. He was—in fact, if not in name—the first public analyst. Not only in the years 1851 to 1855 did he advance microscopical technique, but he also developed analytical methods greatly in advance of any previously known. During the six years from 1850 to 1856 Hassall examined over 3,000 samples of the more important foods, as well as many drugs, and found that at least 65 per cent of them were adulterated.

In 1872 the 1860 act was superseded by the "Adulteration of Food and Drugs Act, 1872." This act extended the right of appointing analysts to boroughs having separate police establishments and included a provision whereby inspectors of nuisances and other local officers were authorized to procure samples for analysis. General dissatisfaction with the act led, however, to the appointment of another Parliamentary committee, whose labors extended only over some 14 days, resulting in a report "deploring the lack of clear understanding of what did and what did not constitute adulteration, lamenting the conflicting decisions and inexperience of analysts, and expressing the opinion that the Act in itself was defective and in need of amendment."

To consider this report two London analysts, Charles Heisch and G. W. Wigner, called together as many colleagues as they could gather, and met on August 7, 1874, at the City Terminus Hotel, London, under the chairmanship of Dr. Theophilus Redwood, professor of chemistry to the Pharmaceutical Society and public analyst for Middlesex. This was a historic meeting, for one of its results was the formation of the Society of Public Analysts. At a meeting on December 1, 1874, at which 17 public analysts were present, Redwood was elected as first president of the society, and a constitution and code of rules were adopted.

One of the first actions of the council of the society, in 1874 and 1875, was to draw up the following definitions of adulteration. An article was to be deemed adulterated: (1) if it contained any ingredient which might render such article injurious to the health of a consumer; (2) if it contained any substance that sensibly increased its weight, bulk or strength or gave it a fictitious value, unless the amount of such substance present was due to circumstances necessarily appertaining to its conclusion or manufacture, or was necessary for its preservation, or unless the presence thereof was acknowledged at the time of sale; (3) if any important constituent had been wholly or in part abstracted or omitted, unless acknowledgment of such abstraction or omission was made at the time of sale; or (4) if it was an imitation of or was sold under the name of another article.

A drug was to be deemed adulterated: (1) if, when retailed for sale under a name recognized in the *British Pharmacopoeia* it was not equal in purity and strength to the standard laid down in that work, or (2) if, when sold under a name not recognized in the *British Pharmacopoeia* it differed materially from the standard laid down in approved works on materia medica, or the professed standard under which it was sold.

Milk was deemed to be adulterated if it contained less than 9 per cent of nonfatty solids or less than 2.5 per cent of fat. Skim milk was to contain not less than 9 per cent of nonfatty solids; butter, not less than 80 per cent of butterfat; tea, not more than 8 per cent of mineral matter—calculated on the tea's being dried at 100° C.—of which at least 3 per cent should be soluble in water, and the tea as sold should yield at least 30 per cent of extract; cocoa, at least 20 per cent of cocoa fat; and vinegar, not less than 3 per cent of acetic acid.

All these definitions were distributed to metropolitan magistrates, clerks of the peace for counties, clerks of local boards and vestries, and metropolitan medical officers, and submitted to the Parliamentary secretary of the local government board, in view of impending new legislature. This latter action may accordingly be regarded as the first substantial attempt by the society to secure a food adulteration act founded on a knowledge of the composition of foods.

The year 1875 saw a new Sale of Food and Drugs Act and a further external activity of the society in pressing for amendments during the progress of the bill through the House of Commons. The 1875 act made the appointment of public analysts compulsory, but as in those days chemical analysis was mainly carried on in universities

and other teaching institutions, and there were few analysts in private practice as consultants, local authorities frequently appointed medical officers of health to act as public analysts.

The society now included the great majority of the public analysts in its membership and, internally, was concerning itself with matters of analysis. In this connection Bernard Dyer pays tribute to *Outlines of Proximate Analysis* by Professor Prescott, of Michigan, published in 1875, which he regarded as the forerunner of that monumental work *Commercial Organic Analysis*, written by A. H. Allen, one of the illustrious members of the society.

In March, 1876, the first number of the *Analyst*, journal of the society, was published.

Despite its name, the membership of the society was not confined to public analysts, although it was restricted to "analysts in practice" until 1899, when it was broadened to include persons having a bona-fide interest in analytical chemistry. But the appointment as a public analyst was the handiest of instruments for the endeavor to establish the science of analytical chemistry with particular reference to the composition of foods and their methods of analysis. Even so, the work was not limited nor circumscribed; the laboratory of the public analyst was often the center of activities dealing with matters of the health and amenities of the public within the purview of the particular local authority concerned.

The leading men of the society were the pioneers of analytical chemistry. Their work was sound. For instance, the methods laid down for the chemical examination of drinking water by their committee in 1881 still forms the basis of today's methods, and the standard for milk of 3.0 per cent of fat and 8.5 per cent of nonfatty solids on which they decided in 1883—after a considerable amount of investigational work during the course of which a serious error in the then-accepted method of analysis was discovered—was later accepted by the government and is still the standard of the present-day milk regulations. The status of the society was also rapidly being established. As early as 1877 its assistance was sought by the German Government on the question of food adulteration and the legal machinery for its suppression, in view of contemplated legislation in Germany. In 1884 it was responsible for an exhibit of adulterated articles and food adulterants at the International Health Exhibition, and by convening a semipublic meeting in 1893 for the purpose of discussing desirable amendments of the food and drugs act, aroused such

public interest that a select committee of the House of Commons was appointed "to enquire into the working of the Margarine Act, 1887, and the Sale of Food and Drugs Act, 1875, and any Acts amending the same, and to report whether any and, if so, what amendments of the law relating to adulteration are in their opinion desirable."

This committee sat from 1894 to 1896, and the S. P. A. was responsible for many recommenations subsequently embodied in the comprehensive report of the committee issued in July, 1896. For various reasons, however, no legislative action followed until the Sale of Food and Drugs Act, 1899, when the society viewed with concern the fact that their very strong recommendation for the formation of some kind of court or board of reference to deal with questions of definitions, standards and limits for foodstuffs had not been accepted. It is desirable here to draw attention to the early date when first this recommendation was put forward. As the years passed it was put forward again and again. Its intention was clearly and concisely stated by E. R. Bolton in his presidential address in 1927 as a court of reference where disputed points of composition and labeling could be argued and settled under more suitable conditions than before a magistrate.

In fact, such a court of reference was recommended by the Select Committee on Food Products Adulteration in 1896, and extended in the final report of the Royal Commission on Arsenical Poisoning (1903). It may be said that the Food Standards Committee of the Ministry of Food, set up in 1947 to continue the work of a wartime interdepartmental committee, serves this purpose to a considerable extent, but it does not go all the way. There has been a very long interval of time between the early recommendation of the society and even this fruition. It must be conceded that the phraseology of the recommendation varied with the years and the particular conditions appertaining to the time of the pronouncement. Thus, in 1936 the president, John Evans, referred to the fact that the main contention of the society—namely, the necessity for extending statutory powers to establish definitions and standards for articles of food—had been conceded in the 1934 Report of the Departmental Committee on the Composition and Description of Food. Nevertheless, the basic principle of an independent, nonpolitical, advisory body to the government has always been strongly advocated.

In 1899, the rules of the society were revised to include any candidate having a bona-fide interest in analytical chemistry. This

affecting the professional status of the public analyst, in giving evidence before departmental committees and in putting forward recommendations in connection with food acts. As the institute now has a very large membership representing all branches of chemistry, its backing of the society has carried very much weight. There is a standing joint committee of the two bodies at the present day.

Early difficulties in the relationship of public analysts with the Inland Revenue Laboratory at Somerset House—more familiarly known as the government laboratory—constituted by law as a court of reference in cases in which the certificate of a public analyst might be contested, have been resolved, and there is now close cooperation in matters of analytical procedure. In 1919 the existence of the local government board as a department of State was terminated by Parliament, and it was reconstituted with enlarged powers under its present title of the Ministry of Health. The routine work of inspectors of food under that board, in such matters as administration of unsound-food and foreign-meat regulations, the Sale of Food and Drugs Acts, and other measures dealing with food, were transferred to the new authority. Consequently, the duties of public analysts under that board were transferred to the new ministry. However, it does not appear from the records that this transference caused any stir in the society. I have not been able to find any information about the reason for this change of name. It is possible that it was the outcome of some change in direction of thought or purpose. I would suggest that it was not so much a political move, tending away from local government towards centralized control, as a reflection of the advancing view that protection of the public in respect of food matters could no longer be confined to protection against adulteration or sophistication, but must additionally be concerned with ensuring a proper quality in food, having in mind that food is fundamental to the nation's health.

The year 1924 was noteworthy for its evidence of the vitality of the society after some 50 years of existence. A North-of-England Section was constituted. For a long time the more distant members had suffered from the difficulties involved in attendance at our general meetings in London; the establishment of sectional meetings and discussions in the North satisfied a need that had been increasingly felt, and the section quickly became vigorous and flourishing. About the same time a standing committee concerned with uniformity of analytical methods was appointed. During the following years, this com-

mittee dealt with dirt in milk, metallic contamination in food colors, essential oils, milk products, and unsaponifiable matters. In 1936 it was reconstituted as the analytical methods committee. These two committees have been responsible, up to the present date, for the publication of 42 reports, nearly all concerned with foodstuffs, but also including the examination of soaps, the assay of crude substances appearing in the poisons schedules, the evaluation of tragacanth, essential oils, and the examination of detergent preparations.

In 1929 the society collaborated with the Association of British Chemical Manufacturers in recommending permissible limits for the arsenical contamination of coloring matters for foodstuffs, in 1930 with the Food Manufacturers Federation in recommending standards for jams, and in 1935 with the Malt Vinegar Brewers Federation in compiling definitions of the various kinds of vinegar. In 1937, following on the steady development of the North-of-England Section, a Scottish Section of the society was established. During the period from 1944 to 1946, three groups were set up, these being fundamentally different from the sections in that they are subject groups, membership being based on interest in a subject or branch of chemistry, whereas membership of a section was simply geographical.

The society was now rapidly extending its interest to all branches of analytical chemistry. Men and women joined because it provided the readiest opportunity for discussion and publication of purely analytical papers. It had become largely concerned with industrial analysis and research. Even during the war years of 1939 to 1945, while under the authority of the Defence Research Department of the government it accepted responsibility for examination of foodstuffs for contamination with war gases, many members were engaged in war work in other fields. The rapid advance in the knowledge and application of scientific methods had resulted in specialization, and our society grasped the opportunity afforded by this development by setting up the three subject groups—microchemistry, an analytical advance without which much of the progress of biochemistry with its requirements for intimate knowledge of the composition of minute vital bodies, such as chromosomes and genes, could not have been made; physical methods, whereby, among other issues, those of instrumentation have gone far to do away with the difficulties arising from the limitations of the hand and eye; and biological methods, wherein even the vital activities of unicellular micro-organisms are employed as analytical reagents. It thereby, in fact, acknowledged the change that had been

slowly taking place in the fundamental objects of the society, namely, the change from a society largely concerned with food, and its composition and analysis, to a society engaged in the promulgation of the science of analytical chemistry.

It was natural that the change should be accompanied by a movement among many members to alter the name of the society to one more indicative of the new conception of its purpose and scope, and to remove from its memorandum and articles of association references to professional objects. To this end a resolution was submitted in these terms to members at a general meeting in 1949, but failed to get the necessary legal three-quarters majority for this purpose, although there was actually a majority in favor of the resolution.

Since then, however, two new factors have emerged. One was an announcement by the government of the intention to found a scientific center in London, followed by a statement by Sir Robert Robinson, in his presidential address at the anniversary meeting of the Royal Society, that this scientific center would be housed in a worthy and impressive building; that the quarters of the various participating societies would be separate, each retaining its own library; and that there would be some 16 societies to enjoy these privileges. The second factor was a general desire of the public-analyst members of the society to form a separate professional organization, The Association of Public Analysts. (At the time of writing of this article, the association had just been registered by the board of trade.)

With regard to the first factor: Our society was not included among the 16 societies nominated by the Royal Society for inclusion in the science center, a fact that most of us regretted.

With regard to the second factor: It must be emphasized that this was in no sense a split in the society—it is anticipated that all the members of the association will remain members of the parent body—but was an attempt by the public analysts to have a society of their own for the purpose of professional advantages. Nevertheless, from the point of view of the movement within the parent body, this action by the public analysts served the purpose of opening up the possibility of removing certain professional objects from the parent society's memorandum of association without hurting the status of any of its members. Also, it additionally served a purpose in assisting any future application for inclusion of the parent body in the science center, inasmuch as our society could then be described as "pure" in the

sense of being without any professional objects and being dedicated solely to the advance of the science of analytical chemistry.

The position within the Society of Public Analysts and Other Analytical Chemists, at the time of writing, is that once again a meeting will be convened to ask members to agree to the change of name to "The Society for Analytical Chemistry." It is now confidently expected that this change will be agreed to at the meeting, and that the society will come into life in 1954.

Before closing this tale of the history of our society, I would refer briefly to the journal of the society, *The Analyst*. This was first described on its title page as "*The Analyst*, including the proceedings of the Society of Public Analysts—a monthly journal of analytical chemistry." This was changed in the second volume to: "*The Analyst*, including the proceedings of the Society of Public Analysts, a monthly journal for the information of those interested in the purity of food and drugs and in general microscopical research." In 1891 there was a significant change, however, for it was then announced as "the organ of the Society of Public Analysts, a monthly journal devoted to the advancement of analytical chemistry." Now its title page reads: "*The Analyst*.—A monthly journal dealing with all branches of Analytical Chemistry: the journal of the Society of Public Analysts and Other Analytical Chemists."

The earlier emphasis on "proceedings" may be a little misleading, suggesting domestic discussions, but reports of proceedings were in fact essentially accounts of the presentation of papers read at meetings and the ensuing discussions; domestic matters occupied but little space. Additionally, space was allotted to official pronouncements, notes on laboratory practice, summaries of departmental reports—both British and foreign—and to interesting or informative accounts of legal proceedings. Very early, too, abstracts of analytical methods published in other scientific journals began to appear. In due course, these abstracts developed a characteristic personal to the *Analyst*—they were all "working abstracts," that is, the method of analysis given in the abstract could, if necessary, be carried out by any skilled analyst without reference to the original publication. They became a recognized feature of the journal, often occupying more than half the space of an issue. Year by year the *Analyst* grew in size and reputation until now it may quite fairly be said that it is the premier journal devoted to analytical chemistry in the United Kingdom, and is recognized as such throughout the world. It is on the same level with us

as is *Analytical Chemistry* in the United States. The year 1949 marked one new departure, however. At the end of that year abstracts were divorced from the *Analyst*, and issued by the bureau of abstracts as a separate publication entitled *British Abstracts C*. But this diversion is proving to be brief; the bureau of abstracts is being closed down, and once again the society will be responsible for the publication of these abstracts, now under the name *Analytical Abstracts*, but still as a separate monthly issue.

The year 1954 should therefore see the advent of the society under its new name of the "Society for Analytical Chemistry," operating its own publication of *Analytical Abstracts*. At the same time, public analysts will establish their own professional body, The Association of Public Analysts.

Legal Position of Public Analyst

In his address to a joint meeting of the American and Canadian Bar Associations in September, 1950, Charles A. Adams, of the Ministry of Food, England, speaking about the legal position of the public analyst in the United Kingdom, said:

> Each food and drugs authority must appoint a public analyst, whose appointment requires the approval of the Minister of Food. The academic qualifications required by a public analyst, who may serve more than one Food and Drugs authority, are laid down in official regulations. There are over 200 Food and Drugs authorities in the United Kingdom, and about 120 public analysts, which latter figure does not include members of the technical staff of the actual Public Analyst holding the official appointment. Each and every public analyst is an independent expert, and is therefore in a position to report to his food and drugs authority on any sample without regard to the views which might be held by other public analysts. The authority decides what action shall be taken on the analyst's report. If legal proceedings are instituted, the case is heard locally by a Court of Summary Jurisdiction, which, perhaps I should remind you, is not a Court of Record. It is not until an appeal from this court is heard by a higher court that case law, comparable in authority with your regulations, becomes established.[4]

This summary states the legal position of the public analyst so concisely yet so clearly that I have felt compelled to quote it in full. There is, however, one feature of the appointment of public analysts to which no reference is made: A public analyst may be employed as full-time officer of his authority or he may be in private practice as an analytical chemist and consultant and carry out his work as a part-time public analyst in his own laboratory. Originally, all public analysts were appointed as part-time analysts. With the passing of time

[4] 5 FOOD DRUG COSMETIC LAW JOURNAL 642 (1950).

and the consequential increase of interest in nutrition and food, however, a number of county and borough councils set up their own laboratories and appointed full-time officers. (The Food and Drugs Act, 1938, delegates the power to appoint public analysts to food and drugs authorities, and defines such an authority as a local authority having a population of 40,000 or upward. The expression "local authority" means not only county and borough councils, but also includes the common council of the City of London, noncounty boroughs and urban districts.)

At the present time, the total number of public analysts in England and Scotland is only a little more than 100, and of these less than one quarter are full-time officers. The fact that these two classes of analysts still remain in existence is probably of some outside interest—or perhaps it would be truer to say that the interest is in the fact that the part-time analyst still remains in existence. Early in the history of my society, as given above, I referred to the public analyst's laboratory as the center of activities dealing with matters of public health. The activities have a wider range than this, however. J. B. Firth,[5] discussing the history of the police or forensic laboratories, gives his opinion that, following the Food and Drugs Act, 1872, the public analyst came to be regarded as the local scientist and, for this reason, he was frequently asked to give assistance in problems requiring scientific investigation, of which the commonest were those relating to crime; he might be asked to make toxicological examinations, to identify stains or to examine various exhibits in criminal cases as the local police might require.

It was only after 1935, when the first police laboratory was set up at Hendon, that this particular kind of work slowly disappeared. But the police laboratories are primarily concerned with incidents or cases that may ultimately become murder charges; where the possibilities lie between suicide and accidental death, the services of the public analyst are still requested. Here we see one activity of the public analyst outside the work strictly appertaining to the food and drugs act. Again, as a consultant, he is called on for assistance in problems arising from the manufacture, processing and packing of human and animal foodstuffs, drugs, poisons, preservatives, disinfectants and detergents. He is generally responsible for the examination of river and stream water in respect of pollution by sewage or trade affluents; the analytical work involved in the study of atmospheric

[5] *Journal of the Royal Institute of Chemistry* (1953).

pollution; the examination of rag flock and other bed material for filth; and advice on occasional problems concerning the suitability of soil for building operations. In the work of his private practice he will probably have occasion to analyze, continuously, samples of some raw or manufactured foods or similar commodities so that in due course he obtains a very detailed and specialized knowledge of their composition and characteristics. It is on the grounds of the comprehensive and intimate knowledge that he thus obtains as a consultant in his private practice, and the ability thereby to bring specialized judgment to bear on the results of analysis of doubtful or adulterated samples taken under the act, that it can be quite properly claimed that the part-time analyst fully justifies his existence.

For years the question of the future of public analysts generally has been under discussion; it is suggested by some that the present position must disappear, and the food and drugs act must be enforced by analysts in regional laboratories. The great argument in favor of such future action is that instrumentation has advanced to such an extent that the private or even the county laboratories will no longer be able to meet the cost of the full equipment. This is true to a large extent, but can be met by cooperation among analysts. In fact, initial efforts in such action are now being undertaken. In my view, the regionalizing in central laboratories of the work of official food analysis would be a loss to public service.

The description "public analyst" originated in the food and drugs act as the person appointed by a food and drugs authority to be the analyst of food and drugs within its area. His appointment and its termination were subject originally to the agreement of the Minister of Health, but are now subject to the Minister of Food. The public analyst does not obtain his own samples; these are obtained by sampling officers of his authority. Formal samples are taken in accordance with the provision of the act. Each sample is divided into three portions in the shop or place where purchased or obtained. One portion is left with the vendor or owner, one is passed to the public analyst and the third is kept for analysis in the government laboratory, if so ordered by a court. Informal samples are taken occasionally for investigational or exploratory purposes, but no legal action can be taken on them.

Nowadays, the public analyst is accepted as a chemist competent to serve official purposes other than those pertinent to the food and drugs act; he is accepted as being able to assist in very many material

issues of public health. His certificate of analysis is admissible as evidence in the courts under the Pharmacy and Medicines Act, the Pharmacy and Poisons Act, the Public Health (preservatives, etc. in food) Regulations, the various milk regulations, food-standards orders, the Labelling of Food Order, and the Rag Flock Act. It may be that he comes in for occasional exceptional responsibility, as in the identification of red petrol. During the war period, petrol was rationed to private motorists but, for certain necessary commercial purposes, there was no such restriction. To assist in controlling the issue of petrol the commercial brand was colored red with dyestuffs. The allowance of ordinary petrol to private motorists, even with any special allowance for business purposes, was naturally very meagre, and there was a great temptation to use red petrol illegitimately. Accordingly, the police were permitted to stop any private car on the road and test the petrol in the tank on the spot. In the case of a presumptive positive test for red petrol, samples would be taken by the police and submitted to the public analyst for his further test. On his certificate of analysis where red petrol was found to be present, proceedings in court could be taken against the offender.

The public analyst must necessarily be of service to his food authority in the field of food legislation. It is difficult to see how certain sections of the act could be interpreted as to form the basis of administrative or legal action without the aid of the analyst. Section (1) of the act deals with foods injurious to health. This raises the difficult question: What constitutes injury to health?

A poison may be present in such small amounts as certainly to be innocuous, unless considered as possibly cumulative, but generally there is no knowledge of where to draw the line between safe and potentially harmful amounts, that is, the amounts of the maximum safe traces are unknown. While medical men have known for a long time what the lethal or immediately harmful amounts of poisons, such as arsenic, lead and similar metals, are, it is only recently that the possibility of harm due to traces of such has attracted any serious attention. Yet within the last decade the science of analytical chemistry has developed and advanced to such a degree of precision and sensitivity that it is now demonstrable that practically all foods contain traces of these so-called poisonous elements, although whether they are naturally present or as the result of contamination during manufacture, processing or other commercial treatment it may not be safe to say. It requires the knowledge of a chemist to find a way through

such a labyrinth of doubt. Again, one man's meat is another man's poison. On the face of it, a really ripe Stilton cheese must be regarded with the greatest suspicion, having regard to the universal condemnation of moldy and decomposing meat as unfit for human consumption. This, however, brings us up against the game which is hung until it is "high." And so it goes on! The lawyer quite properly will generally transfer the onus of opinion in these matters to the analyst; the latter must be prepared to meet the challenge.

To take another example: Section (3) of the act deals with the sale, to the prejudice of the purchaser, of a food not of the nature, substance or quality of the article demanded. It may be said that, generally speaking, a purchaser is in a position to know whether or not the article is of the nature demanded. It is another matter with substance or quality. Margarine, as now manufactured, can be said to be of the nature of butter, except possibly to those somewhat exceptional persons who can distinguish by taste. But it is not of the substance or quality of butter. There is no difficulty about that. Equally, there is no difficulty about butter containing an excess of water. There would be a very real difficulty, however, about butter containing a small amount of unsaponifiable matter if the question arose: Does this butter contain mineral oil? The answer might well be simply an opinion of the analyst. Finally, in this matter of legal-mindedness, a public analyst must be well prepared to stand up to cross-examination in court on his opinion that the label of a food is false and misleading in its particulars, in the statements advanced or in the inferences or conclusions drawn from the advertisement claim.

Just as in the early nineties the analyst had rendered public service by his work implementing the then-new laws against food adulteration, so during the second World War the public analyst in effect repeated this service. The shortage of food and its consequent rationing resulted—if not inevitably, at least not unexpectedly—in the putting on the market of all sorts of food substitutes. Also not unexpectedly, many of these were of a fraudulent character, so much so that the Ministry of Food in 1941 was compelled to bring into force a food-substitutes order to control this activity. Despite this order the market was flooded with substitute articles. One of the honest attempts which nevertheless resulted in considerable litigation, because of its accompanying claims for food and nutritional values similar to those of the egg, was the production of cake mixtures containing soya flour to replace the missing egg. Another such effort

was the milk substitute, an article compounded of a minimum of 50 per cent of soya flour with water; this was only permitted for manufacturing purposes and not for sale to the public. An article of doubtful value but extensively used was the "fat extender," a mixture of oil or fat and water prepared with the aid of an emulsifying agent. The composition of this article occasionally suggested the old familiar attempt to make a bar of water stand on end. A not-so-honest preparation was colored and flavored water sold as onion extract.

A specious production causing considerable concern at the time was brought to light by the fact that some United States servicemen in camp in a country district, who had attended a Saturday evening dance in the neighbouring village, were found to be *hors de combat* not only on the following Sunday but also on Monday. Inquiry established that these men had all responded handsomely to the offer of a cheap brand of wine, and that the illness of the following two days was marked by an exceptionally prolonged period of stupor or semi-coma. Analysis proved the presence of methyl alcohol in the wine, thus accounting for the prolonged "drunkenness," it being known from poisoning cases in the past that this effect, together with a tendency to blindness, was a characteristic result of drinking methyl alcohol. Subsequently it was established that the wine had been manufactured by fortifying some sort of fermented fruit with industrial methylated spirit.

All this meant, in effect, that the public analyst had again to do pioneer work in the identification and determination of what in many instances were new forms of food adulteration. He rose to the occasion and it was largely by his help that this activity was generally kept under control.

Charles A. Adams in his address before the Division of Food, Drug and Cosmetic Law of the American Bar Association, September 20, 1951,[6] ventured the prophecy that with the forthcoming amendment of our food and drugs act there will be seen a decreasing divergence from the North American pattern. To implement international agreement, however, practice must march with principle. If the pattern of English practice that I have endeavored to sketch above has any value as offering a means of comparison with United States practice then, indeed, international agreement may be one step nearer.

[The End]

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[6] 6 FOOD DRUG COSMETIC LAW JOURNAL 893, 902 (1951).

By WILLIAM W. GOODRICH

Enforcement and Judicial

NO CASE DECIDED during the past year had the serious impact of the *Cardiff* [1] decision. Yet the flow of judicial opinions was at least as high as in any recent year.

A new law was enacted to restore the authority for mandatory factory inspections, after this important legislation was given impetus by the recommendation of President Eisenhower in his first state-of-the-Union message. The controversy over the scope of the authority granted by the new law is now a matter of history.

Factory-Inspection Cases

There were no cases in 1953 which involved the new inspection act. But the effect of the *Cardiff* decision on inspections conducted before the passage of the amendatory legislation was considered in two important cases.

One of these cases arose in the Ninth Circuit where the factory-inspection provisions were first declared invalid.[2] It was a criminal prosecution involving a food alleged to be violative because it consisted in part of filth and because it had been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth. Both the corporation and the individual were convicted in the trial court and, on appeal, challenged two vital rulings.

[1] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7246, 344 U. S. 174.

[2] *Golden Grain Macaroni Products Company v. U. S.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7273 (CA-9, December 28, 1953).

Progress in 1953

Mr. Goodrich Delivered This Address Before the Ninth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association Held in New York City January 27, 1954. He Is Assistant General Counsel, Department of Health, Education, and Welfare

First, it was argued that evidence obtained through factory inspection under the original grant of inspection authority could not be used because the *Cardiff* decision had declared the law unconstitutional. Second, the defendants contended that the inspectors had obtained permission to inspect from a person without actual authority to grant it.

The court of appeals ignored the arguments based on the *Cardiff* case, pointing out that the original law authorized inspections if permission were first obtained. Moreover, the court said: "The authority of the Administrator [Secretary] to make investigations of this nature is broadly granted." For this statement, Section 702 (a) was cited as supplementing the factory-inspection grant. The inspection actually conducted, and here upheld, included a thorough examination of the manufacturing process, sampling of raw and finished materials and of moths, larvae, etc., photographing of the plant conditions, and determination of interstate consignees.

The more seriously pressed argument was that the company's sales manager, who granted permission to inspect, was without actual authority to do so. But since the inspectors had been directed to him as the person in charge by the production manager and by the clerical

staff, the court found that he was the custodian of the plant at the time. The appellate court characterized the claimed lack of authority as "in the last degree technical."

The court of appeals ruled, also, that the company's president was criminally responsible for the violations even though he was absent from the plant when some of the shipments were made. The food involved in one count was manufactured and packed before the president's departure, and another of the shipments was made the day after his return. The insanitary conditions, the court said, "had certainly prevailed for a considerable length of time prior to his [the president's] departure," and were chargeable to him.[3] In passing, the court reaffirmed the holding in *Berger v. U. S.*[4] that Section 402 (a) (4) was not unconstitutional for vagueness.

The other significant inspection case was *U. S. v. Arnold's Pharmacy, Inc.*[5] There the admissibility of evidence obtained during an inspection was challenged by a motion to suppress. The defendants resisted the use of samples, shipping records and prescription records, claiming that they were obtained in violation of the Fourth Amendment and, if not, then they were obtained under Section 703 of the Act which grants immunity from prosecution. This section authorized inspectors, upon written request, to have access to and copy interstate records. After a hearing on the motion, the court concluded that the defendants had willingly turned over the samples and records, and had voluntarily made statements and permitted photographs to be taken. Because of the voluntary nature of their conduct, it was held that the Fourth Amendment had not been violated. Nor could the immunity clause of Section 703 be invoked, the court said, since it is applicable only in cases where a written request was necessary to compel a person to permit access to and copying of records. Here the shipping and prescription records were obtained by virtue of the permission granted by the corporate owner and its authorized agent.[6] The court said that:

[3] Because of the impressive character of the evidence connecting the president, one Dedomenico, with the violative shipments, the court found it unnecessary to rest its decision "on the settled rule" that the "criminal responsibility of a corporate officer having broad authority such as that possessed by the defendant does not depend upon his physical presence."

[4] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7248, 200 F. (2d) 818 (CA-8, 1952).

[5] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7269, 116 F. Supp. 310 (DC N. J., 1953).

[6] On January 19, 1954, Judge Smith, of the District of New Jersey rendered an opinion on the same point to the same effect as the *Arnold Pharmacy* case. (Criminal No. 268-53 (DC N. J., 1954).) That case involved samples of drugs, specimens of labels, copies of advertisements, and information obtained upon examination of the defendant's records containing names and addresses of interstate consignees.

. . . if the person holding the drug and the records refuses access and copying, the statute makes it mandatory upon him to accede, and if he fails to accede after being served such a statement in writing, he is subject to a specific penalty . . . Since the evidence here was voluntarily turned over to the Government by its owners, the conditions for the applicability of the statutory provision in question do not exist, and the statute does not apply.

The court also sustained the indictment against the charge that the provisions of the Durham-Humphrey Amendment, Section 503 (b) (1) (A), were vague and contradictory.

Adulterated Food

An adverse decision in the district court in *U. S. v. 449 Cases . . . Tomato Paste*[7] resulted, we believe, from an erroneous holding that partly rotten food can be condemned only on a showing that the food is so rotten that it would be injurious to health or inedible.

The cans in the shipment were first sampled and examined when imported in April, 1951, but were released. In July, a new sample was taken after an inspector noted that some cans in the lot had been resoldered. The new analyses, made by the mold-count method, gave widely varying results, but showed beyond dispute that at least some of the food was partly rotten. Claimant's analyses also varied somewhat, but its chemists admitted that the food contained some rotten material.

Influenced by the fact that the food had been released after the import examination and by the "discrepancy" in the analytical results, the district court held the food not adulterated. The decision was cast in terms of burden of proof, the court holding that the initial release greatly increased the government's burden, and that the burden could not thereafter be carried successfully without proof that the food was injurious to health or plainly inedible.

At, or very shortly after, the end of the trial, the government discovered that some cans in the lot were exploding from extensive chemical decomposition. A motion for a new trial on this newly discovered evidence was denied because the evidence should have been discovered earlier. An appeal is now pending in the Second Circuit.

[7] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7255, 111 F. Supp. 478 (DC N. Y., 1953).

Economic Adulteration

The *Black-Eyed Peas* case involved adulteration by substitution of a disproportionate amount of liquid packing medium for peas.[8] The court concluded that even in the absence of a standard of fill of container, the canned food was adulterated unless the container was filled with peas to the degree that "can be achieved by the use of proper and feasible commercial practices." The amount of packing medium could not exceed the amount necessary for "properly processing and preserving the food." A greater amount is an economic adulteration.[9]

Misbranded Foods

Imitation Foods.—An opinion from the Northern District of New York was the first explaining what an "imitation" food is. (See Section 403 (c).) In *U. S. v. 651 Cases "Chocolate Chil-Zert,"* [10] the libel alleged that a vegetable-fat frozen dessert, plainly marked "not an ice cream" and "contains no milk or milk fat" was misbranded because it was not labeled with the word "imitation."

Procedurally, the case illustrated the usefulness of the discovery process in establishing uncontested facts and, where possible, submitting the case on motions for summary judgment. The government served claimant with requests for admissions to establish the close resemblance of this article to ice cream. On the admissions, the court found:

> Chil-Zert is identical with ice cream in its method of manufacture, packaging and sale. It is similar in taste, appearance, color, texture, body and melting qualities. It has identical uses; its composition differs only from ice cream in the substitution of a cheaper ingredient; namely, vegetable oil in place of milk products. It is, therefore, something less than the genuine article chocolate ice cream. It is inescapable that the ordinary understanding of English speech would denominate it as an imitation of ice cream.

Recognizing that actual deception was not involved in the labeling of Chil-Zert, the court stated that truthful labeling would not excuse the food from the Congressional demand that it be labeled an imitation. The decision has been severely criticized, but if the imitation provisions do not cover this case, it is difficult to think of a case in which they would apply.[11]

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[8] *U. S. v. 149 Cases "Silver Brand . . . Black Eyed Peas,"* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7278, Civil No. 3689 (DC Colo., 1953).

[9] Cf. *U. S. v. 116 Boxes Arden Candy Drops,* 80 F. Supp. 911 (DC Mass., 1948), involving a charge of misbranding under Section 403(d) because of slack-filling.

[10] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7272, 114 F. Supp. 430 (DC N. Y., 1953).

[11] Williams "New Products for Old Uses," 8 FOOD DRUG COSMETIC LAW JOURNAL 587 (September, 1953).

Net-Weight Declaration.—The validity of Section 403 (e) (2), requiring an accurate statement of net weight on packaged food, was sustained against a contention that the law was vague and indefinite.[12] The motion to dismiss claimed that since the Administrator (now the Secretary) is required to issue regulations permitting reasonable variations from the net-weight declaration, this introduces uncertainty into the law, making it impossible for shippers to know whether the law applies to their products. On the authority of *U. S. v. Shreveport Grain & Elevator Company*,[13] the court held the statute sufficiently definite, and held that the regulations issued properly "establish adequate standards permitting reasonable variations."

Food Standards

In *Reade v. Ewing*,[14] the Court of Appeals for the Second Circuit upheld an order allowing the use of synthetic Vitamin A as an optional ingredient in oleomargarine. In so doing, however, the court rejected our contention that the petitioner had no standing to obtain judicial review, solely by reason of his interest as a member of the consuming public.[15]

Reade's position was likened to that of a "private Attorney-General" authorized by Congress to "vindicate the right of the United States against its wrongdoing officer." This holding has unfortunate implications, we believe. Under it, there are potentially 160 million private citizens who may challenge a food-standards order as persons "adversely affected." While the number of those sufficiently interested to bring suit is undoubtedly very much smaller, it is no exaggeration to contemplate the prospect of several reviews after the issuance of each regulation. Review may even be sought by persons who have not participated in the hearing, or who have no interest in the litigation aside from eating the food in question.

It seems to us that the court's decision is a marked departure from the traditional rule limiting the judicial power to contesting

[12] No. 222, Criminal (DC Wis., 1953).

[13] 287 U. S. 77 (1932).

[14] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7261, 205 F. (2d) 630 (CA-2, 1953).

[15] Petitioner had also alleged that as a producer of natural Vitamin A, he had sufficient standing to challenge the order. The court did not discuss this point in view of its decision that he was adversely affected as a consumer.

The court's decision was based on the following statement in Reade's petition: "In addition, your petitioner and the members of his family are consumers and prospective consumers of oleomargarine and the inclusion of any harmful ingredient therein which will make or which may make the oleomargarine unwholesome and detrimental to the health of a human being, will adversely affect and harm petitioner and the members of his family."

parties, with vital and direct interests in the outcome of the action, who have raised pertinent issues in the administrative process that resulted in the challenged orders.

Drugs

One court held that cigarettes may properly be regarded as drugs if labeling claims of curative or preventive effects are made. In *U. S. v. 46 Cartons "Fairfax Cigarettes,"* [16] the claimant argued that cigarettes were not "drugs," saying that the labeling merely promised to "increase one's smoking pleasure."

We contended, in contrast, that the accompanying circular made extensive therapeutic claims for a host of diseases. The court said:

> The extensive reference to "miracle vapor" and its seeming effects in the reduction of the frequency of respiratory diseases, and the somewhat more than casual references to the diseases aforementioned, would appear to have no other purpose than to mislead the unwary.

The "subtle appeal" which the labeling made to the natural desire of people to avoid diseases classified these cigarettes as a drug, within the meaning of the Act.

U. S. v. 38 Dozen Bottles of Tryptacin [17] is an excellent example of a drug misbranded because it was advertised for one thing and labeled for another. The labeling failed to bear adequate directions for use because it did not contain directions for the conditions for which Tryptacin was advertised to the public.

The bottle labels offered the article as an antacid—an aid in the relief of excess gastric acidity. But the full-page newspaper advertisements prominently featured "stomach ulcers," men in white, patients in great distress and a diagramatic drawing of the human stomach, together with a bold statement that in clinical tests with ulcer patients there had been "almost complete healing."

The defense was grounded on the claim that the advertisement offered Tryptacin for temporary palliative relief and for nothing more. This was based on reading the advertisement quite literally and ignoring its obvious purpose and true meaning. Viewing the ad as a whole, the court termed the claimant's interpretation an "unreasonable" one and the ad completely out of place for a simple antacid.

[16] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7263, 113 F. Supp. 336 (DC N. J., 1953).

[17] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7264, 114 F. Supp. 461 (DC Minn., 1953).

In this case we introduced the practice of using experts in advertising and market psychology to prove what the true meaning of the promotional material would be to prospective purchasers. Two experts testified, both on expert knowledge and on a psychological survey conducted with 200 individuals, that the advertisement actually offered the drug as a cure for stomach ulcers, even though it was labeled as an antacid. The ever-increasing use of labeling and advertising material with claims of subtle emphasis and meaning, as contrasted with direct curative representations, may bring this relatively new field of expert knowledge into much wider use in proving our cases.

Hoxsey Case

We encountered procedural difficulties in finally obtaining a satisfactory injunctive decree in *U. S. v. Hoxsey Cancer Clinic*.[18]

In June, 1953, Judge Atwell, over the government's objection, signed a decree of injunction presented by defense counsel. The decree allowed shipments of the Hoxsey drugs as a cancer cure if the labeling bore "appropriate qualifying statements revealing the conflict of medical opinion as to the efficacy of the drug in the treatment of cancer."

On our petition for a writ of mandamus,[19] the court of appeals agreed that the decree was in direct conflict with its earlier mandate, saying:

> Instead, however, of signing the order as presented [by the Government], he added to it language which had the effect of emasculating, if not of completely nullifying, the mandate. This is made plain not only by a comparison of mandate and decree, but by respondent's answer . . . . Thus reasserting the correctness of his judgment, which this court had reversed, and the incorrectness of our judgment reversing it, the respondent instead of confessing error in not accepting the giving effect in his decree to the judgment of reversal, defends the reinstatement of his own judgment . . . . This he may not do.[20]

In October, the district court signed a decree revised in accordance with the directions of the court of appeals, flatly prohibiting interstate distribution of the Hoxsey drugs as a cure for cancer.

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[18] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7235, 198 F. (2d) 273, cert. den., 344 U. S. 928.

[19] At this time, the defendants had filed a notice of appeal from the order granting a decree of permanent injunction. In November, 1953, they applied for an order suspending the decree of injunction pending appeal. This was denied.

[20] In *In re United States of America*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7267, 207 F. (2d) 567 (CA-5, 1953), the defendants' petition for certiorari based on the failure of the court of appeals to permit them to intervene in the mandamus proceedings was denied.

Res Judicata and Summary Judgment

In *U. S. v. "Blake's Mineral Compound,"* [21] the court granted the government's motion for summary judgment, holding that *res judicata* barred the claimant from contesting a charge of "false and misleading" against labeling which, though not identical, was substantially the same as labeling determined in a prior seizure to be false. Obviously, a seizure action would have little meaning if a slight modification of the claims could give the claimant a fresh opportunity to litigate the question of falsity.

The article involved was labeled "Blake's Mineral Compound" and was represented as being effective in preventing and treating bloat in sheep and cattle. In 1945, after trial, a court in another district had determined that the same article, under the name of "Blake's Stop-Bloat Chemical," was falsely represented as being effective in preventing bloat. The prior adjudication was held sufficient to entitle the government to summary judgment.

This is practical application of the principle of *res judicata*. Since it was clear that the same claims were being made and since the claimants in both actions were in privity, the fact that the labeling was not identical in every respect was not controlling. Thus, mere technical changes in the wording of promotional material will not open the way for relitigation of the truth or falsity of claims where that issue has once been decided.

Interstate Commerce

The aftermath of the 1951 Kansas City flood presented the Food and Drug Administration with many problems, not the least interesting of which was the seizure of 1,800 wine gallons of distilled spirits.[22] This cache was located, on the date of the flood (July 13, 1951) in the Last Chance Tavern and the Shawnee Club and was there inundated by the filthy flood waters. The labels and tax stamps were mutilated and washed from the bottles, and the bottles were caked with filth from the receding waters.

Claimant had the bottles removed to his home. Seizure of this lot was effected on a charge that the spirits had been "held for sale" under insanitary conditions whereby they may have been contaminated with filth.

[21] No. 2927 (DC Ida., April 7, 1953).

[22] *U. S. v. 1,800 Wine Gallons of Distilled Spirits and 2,613 Wine Gallons of Wine*, No. 8178 (DC Mo., January 11, 1954).

In moving for summary judgment, claimant argued that, after the liquor was moved from the tavern to his home, it was no longer held for sale. He said it was stored at his home "for safe keeping and for no other purpose." Rejecting this contention, the court observed at the outset: "This is a horse that is easily curried!" Closing the tavern on the day of the flood, so that no sales were subsequently made, did not remove the liquor from the reach of the Act.

The court was persuaded, by the failure of the claimant to show that he had voluntarily ceased business at that time or that he intended to hold 1,800 gallons of liquor for his own personal consumption, that the liquor was held for sale after the adulteration occurred.

This opinion emphasizes that the "held for sale" provision of Section 304 is primarily jurisdictional, and that the government is not compelled to prove an actual sale or a specific intended sale in order to seize the article.

Removal for Trial

The issues involved in removal and transfer of seizure actions for trial provided three written opinions this past year.

In *Ridd Laboratories, Inc. v. U. S.*,[23] the claimant had moved on the date of trial, under Section 304(a), for removal from the Northern District of Texas to a district of reasonable proximity to his principal place of business. Without specifying the basis for its decision, the court refused to permit the removal.

On appeal, the government urged that the motion was properly denied because it was not "seasonably make" as the statute requires. The court of appeals did not discuss this, but reversed the judgment on the ground that the statute compels removal where, as here, no good cause to the contrary was shown. Under Section 304(a), then, the district court's discretion in denying applications for removal is closely restricted, absent evidence showing strong grounds for resisting removal.

A seizure of "Mountain Valley Mineral Water" in the Western District of Tennessee resulted in a series of transfers which moved the case from Tennessee to the Eastern District of Arkansas, then to the Western District of Arkansas and then back again to the eastern district, where it now rests.

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[23] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7254, 203 F. (2d) 217 (CA-5, 1953).

The claimant's principal place of business is Hot Springs, in the Western District of Arkansas. Over the government's objection, claimant succeeded in moving the cause from Tennessee to the eastern district. Subsequently, by stipulation, the case was retransferred to the Western District of Arkansas. But there the court, on its own motion, remanded the case to the eastern district. In two well-reasoned opinions, the district court in western Arkansas held that it lacked jurisdiction.[24] The right to removal under Section 304 is limited, it held, to a single application made to the court of original jurisdiction. When the claimant had the case transferred from Tennessee to eastern Arkansas on motion, it "exhausted the statutory right to transfer." The case could not thereafter be transferred again either on motion or by stipulation. The court perceived that any contrary rule would make it possible for parties to transfer a case as many times as they desired and "thus control the jurisdiction of the Federal courts by various stipulations."

This case should, we believe, place in the "well-settled" category the proposition that the statute authorizes only one transfer of a seizure action, and this excludes the home district of the claimant.

Conclusion

On October 1 we had the greatest number of contested cases in our history. This, I think, accounts for the increasing volume of written opinions, despite the fact that cases now on appeal are at the lowest figure for the past four or five years. **[The End]**

• FOOD PRODUCTS—BROKERAGE FEES •

One of the largest distributors of food products in the Middle West is charged with buying from sellers of food products at "lower net prices" which reflect brokerage. According to the complaint, "one of the major items which determined these lower net prices was the elimination of the cost of brokerage and other sales expense." Normally, the complaint adds, these sellers sold through brokers but in virtually all their dealings with the food distributor, and at its "request and insistence," they sold food products direct, and the savings in the cost of brokerage were reflected in the lower net prices granted the food distributor. (Complaint issued February 1, 1954; released February 11, 1954.)—CCH TRADE REGULATION REPORTS ¶ 11,619.

[24] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7271 (January 7, 1954).

Druggist, Beware!

Absolute Criminal Liability Is Here

By RICHARD C. NELSON

This Paper, Based on the Author's Experience in Enforcing the Federal Act As Assistant United States Attorney in San Francisco, Sounds a Clear Warning to the Owner of the Neighborhood Drugstore

Background

When a clerk in a corner drugstore takes some drugs and puts them into an unlabeled bottle and sells them, few would say that the clerk's employer should go to jail. Assuming that the employer knows nothing about the matter, should he be criminally liable for another's act? Such liability is a fact today—and it should be no surprise to the lawyer well versed in the field of food and drug regulation. Criminal liability in such cases is a result of the development of two concepts of the law over a long period. That each concept would be extended so far, and that together the two would bring vicarious criminal liability to the local druggist, was predictable as long ago as 1948. Nonetheless, it was September of 1953 before that possible prediction became a judicial fact.

Expanding a legal concept to its logical limit and predicting whether a court will go that far is the everyday task of the lawyer. However, even though his logic be excellent, the lawyer's prediction often goes astray. The court may differ from his end result because of stupidity, wisdom or expedience—or it may be that the court will bear the lawyer's prediction out, at least as to end result. Whatever the outcome, where important concepts are involved, an examination of the court's decision is often useful. This paper attempts such a review.

A century ago the law was clear that a crime consisted of two elements: a criminal act and some sort of mental culpability. The

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second element was variously named (intent, knowledge, *mens rea*, etc.), but it was a *sine qua non*. In the last 100 years exceptions have weakened the rule, and it was not a great surprise when the Supreme Court said in 1943 that criminal responsibility under the Federal Food, Drug, and Cosmetic Act[1] required no mental culpability.[2] Indeed, after the decision in the *Dotterweich* case, the mere holding of responsible corporate office seemed to be sufficient to constitute the criminal act. How responsible that office must be was left to the jury in the individual case.[3]

The nonincorporated druggist took little notice of the *Dotterweich* decision for two reasons. First, the decision was rendered under a federal law, and the corner druggist was regulated only by the state. Second, the development of corporation law was not a subject for individual proprietors to worry themselves over. However, another legal concept was developing, and its fruition in 1948 should have brought the *Dotterweich* view of vicarious criminal liability into sharp focus for the small druggist.

The second legal idea which was expanding was the concept of "interstate commerce." That the United States Constitution should be flexible enough to accomplish the goals set forth in its preamble never has been much disputed over the years. Many, however, have

[1] Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, as amended by the Act of June 24, 1948, 62 Stat. 582, 21 USC Sec. 301, and following (1946).

[2] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

[3] "Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. . . . For present purpose it suffices to say that in what the defense characterized as 'a very fair charge' the District Court properly left the question of the responsibility of Dotterweich for the shipment to the jury . . . ." *U. S. v. Dotterweich*, cited at footnote 2, at pp. 284-285.

disputed the legal methods by which this was sought to be done at various times. In seeking a source of legislative power for laws promoting the general welfare, few would have guessed originally that the words in Section 8, Article I, "to regulate commerce . . . among the several states," would become the magic password to steadily increasing federal control over the local affairs of the private citizen. The author has not the skill nor the space to trace the miraculous expansions of the concept of "interstate commerce." It is sufficient here to state that in 1948 the Supreme Court held that the corner druggist was subject to the regulation of the Federal Food, Drug, and Cosmetic Act, if the drugs he dealt with had ever been shipped in interstate commerce.[4] Congress, not knowing how the highest court would decide the case presenting this problem, made the law doubly certain by amending the Act to specify that intervening intrastate sales would not affect its coverage.[5]

The concepts of vicarious criminal liability and interstate commerce had thus developed, after the *Sullivan* decision, to the point where the corner druggist should have become gravely concerned. The two concepts had developed separately, however, and factual distinctions are never hard to find. True, the Supreme Court in the *Dotterweich* and *Sullivan* cases used broad language not limited to specific facts. Nonetheless, those lawyers who foresaw the possibility felt that if a single case required both concepts to be expanded to their indicated limits, a conviction would not be obtained. In late 1953 such a case was presented to a federal judge and jury in California.[6] Their decision puts the question to its rest, at least temporarily.

Case

On June 25, 1953, the United States Attorney for the Northern District of California filed an information charging George Moore and Edgar Holiman with causing certain drugs to become misbranded after they had been shipped in interstate commerce.[7] The information contained three counts, each charging that on a specific date a number of pulvules of Seconal Sodium (which had moved in interstate com-

[4] *U. S. v. Sullivan*, 332 U. S. 689 (1948).

[5] Act of June 24, 1948, cited at footnote 1.

[6] *U. S. v. J. George Moore, an Individual Trading as Moore's Pharmacy, and Edgar H. Holiman, an Individual*, No. 33646, Criminal, in the United States District Court for the Northern District of California, Southern Division (1953).

[7] The offenses charged took place prior to the effective date of the Durham-Humphrey Amendment to the Act, so possible violations based on the fact that *prescription* drugs were involved were not charged. Instead, the information charged that because the pulvules were placed in unlabeled containers they were misbranded under 21 USC Secs. 352(b)(1) and (2), 352(d) and 352(f)(1). Such misbranding becomes an offense under 21 USC Sec. 331(k).

merce) were removed from a properly labeled container and sold in a completely unlabeled container. The information used the statutory language of "causing" and charged the defendants equally. The evidence produced at the trial, however, quickly revealed that, factually speaking, the defendants were not equally involved.

George Moore was the co-owner of the drugstore where the illegal sales were made, and a registered pharmacist. About three months before the misbrandings took place, he hired Edgar Holiman, an old friend and former employee. Moore knew at the time he hired Holiman that Holiman was not licensed to practice pharmacy in California. George Moore knew further that Holiman had just been discharged from a store owned by Donald Moore at the time his store became a drug outlet. Donald Moore was a brother of George Moore and the other co-owner of the drugstore where the illegal sales were made.

George Moore put Holiman to work on the shift with himself. However, George Moore was often absent from the store during his shift and, at such times, the store was left in Holiman's charge. On each of the three occasions when drugs were sold in unlabeled containers, George Moore was out of the store. It was Edgar Holiman who did the acts which caused the drugs to become misbranded after shipment in interstate commerce. Further, there was evidence that Moore had no knowledge of the three sales made by Holiman.

To make the case still more unsympathetic to the jury, the defendant Holiman pled *nolle contendere* prior to the trial and only George Moore was before the court as a defendant. If Moore was to be convicted, the government had to show the jury that Moore had what the *Dotterweich* case called a "responsible share" in the criminal acts. The *Dotterweich* case said that this was a question of fact for the jury in each case. The government attempted to carry its burden of establishing that fact beyond a reasonable doubt by connecting the concept of responsibility to that of management.

The evidence regarding management decisions was weak. Apparently the store nearly ran itself. Work shifts were a matter of convenience; a routine was carried out from years before. All of the pharmacists in the store ordered drugs from the wholesalers. Retail prices were fixed on a scale known to all. But regardless of the manner in which George Moore exercised his authority, the government contended that he *had* managerial authority and, with it, managerial responsibility.

Donald Moore, the other co-owner of the drugstore where the misbrandings occurred, was eliminated as a manager of the store. He came into the store only a few minutes a day. He had previously discharged Holiman from his own store. Little attention was paid to his desires. George Moore, on the other hand, had hired Holiman even though he knew Holiman could not legally practice pharmacy; it was George Moore who left Holiman in charge of the store. There was also testimony that George Moore was regarded as the manager by the employees.

With the major evidence in this balance, the case went to the jury. The defendant had not physically participated in the criminal acts, nor had he known of them. But the court instructed the jury that these were not necessary elements of the crime.[5] The evidence of Moore's absence from the store, under that view of the law, was strong evidence against him. It was the defendant's absence and the incompetence of the man he had hired to work for him which allowed the criminal acts to occur, or so the jury might infer. The fact that George Moore was the manager of the store was not rebutted. It was clear that he had failed to live up to the responsibility of his position as manager of a drugstore. The government contended that this failure was a "responsible share" in the criminal acts of Holiman. The jury agreed and convicted George Moore on all three counts.

Implications

The courts have chosen to interpret the Federal Food, Drug, and Cosmetic Act liberally in order to achieve the degree of consumer protection they believe Congress intended. To a degree rare even among federal regulatory statutes, the scope of the federal law in this field has been continuously widened. Each landmark decision further extending federal jurisdiction over food and drugs has pro-

[5] The court gave the government's twelfth proposed instruction, which was as follows:

"The evidence establishes that the defendant Moore was not present at the time when any of the alleged acts of repacking and dispensing took place. However, under the Food and Drug law, a person may be held criminally liable for violations though he was not physically present and did not participate in the wrongful acts.

"*U. S. v. Dotterweich*, 320 U. S. 277, 281-285 (1943)

"*U. S. v. Kaadt et al.*, 171 F. 2d 600, 604 (7th Cir. 1948)

"*U. S. v. Parfait Powder Puff Co.*, 163 F. 2d 1008, 1009-1010, *cert. den.* 332 U. S. 851.

"Under the Food and Drug law, it is not necessary for the Government to establish that the defendant Moore intended to violate the law, or that he was acting in bad faith, or that he was even aware that the law was being violated.

"*U. S. v. Dotterweich*, 320 U. S. 277, 284-285 (1943)

"*Barnes et al. v. U. S.*, 142 F. 2d 648, 651 (9th Cir. 1944)

"*U. S. v. Greenbaum*, 138 F. 2d 437 (3d Cir. 1943)."

duced a fresh crop of disagreement over the propriety of the judicial interpretation. In part, such disagreement stems from a philosophy of government at odds with endless federal power, regardless of the excellent consumer protection afforded. In part, the disagreements stem from specific cases where many believe the decisions were legally unjustifiable.

The decision in the *Moore* case is pregnant with the seeds of future disagreements. The points of legal controversy became clear in the argument of the defendant's motion to dismiss, made at the end of the government's case. Counsel for the defendant pointed out to the court that the prior decisions on vicarious criminal liability under the Act were limited to corporations.[9] He further argued that in the present case the defendant was not in the large-scale business of interstate selling, but was a small dealer at the far end of the interstate chain. As a final and important point, the defense counsel asked the court how any druggist could protect himself from a criminal charge if George Moore were guilty in this case. The defense put a hypothetical situation to the court: Suppose a druggist exercised every care in management, hired the most qualified personnel, explained and displayed the law to his employees and checked constantly on his clerks. Suppose he did all this and one clerk still managed to sell drugs (which had moved interstate) in an unlabeled container. Under the law as proposed by the government in the *Moore* case, would not the hypothetical druggist also be guilty of a criminal offense? If so, would not that be creation of an absolute liability where it had never been known before?

The court, in effect, held that a druggist under the hypothetical circumstances would be guilty; the defendant's motion to dismiss was denied. The government's side of the argument showed that the harshness of the decision was more apparent than real. First, the prosecutor argued, no such case as the hypothetical one has ever been brought. Second, to prevent such a criminal case from arising, at least four administrative checks are present. The field office of the Federal Food and Drug Administration must hold a preprosecution hearing; its recommendation to Washington could be that no criminal charge be brought. If it recommended prosecution, the legal section in Washington could refuse. If the Food and Drug Administration in Wash-

[9] Defense counsel was essentially correct. The direct holdings that physical presence and intent are not necessary all involved corporations: the *Dotterweich*, *Greenbaum* and *Parfait* cases. As dicta and indirectly, such cases as the *Kaadt* case applied the *Dotterweich* principle to individuals. See the preceding footnote for citations to these cases.

ington agreed on prosecution, the Department of Justice in Washington might refuse to refer the matter for prosecution. If all of these three offices felt prosecution was justified, the United States Attorney, who would probably be closest to the facts, could still decline prosecution.

Counsel for the defendant in the *Moore* case argued that a man's guilt of a criminal charge should not depend on administrative judgment. In answering this, the government contended that the law would make the hypothetical druggist guilty technically, but that if all the mitigating factors of the hypothetical case coincided, administrative judgment would prevent prosecution. The government pointed to the words of the Supreme Court in the *Dotterweich* case:

> To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress . . . would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on "conscience and circumspection in prosecuting officers," *Nash v. United States*, 229 U. S. 373, 378. . . .[19]

The court denied the defense motion and the jury convicted George Moore. Many will take issue with the court's action, but little can be said about the final decision of a jury. All of the legal arguments made in the defense motion were repeated in modified form to the jury. Perhaps the bare fact that 12 peers of George Moore agreed on his guilt is answer enough to the legal contentions of the defense. In view of the vital importance of adequate safeguards for food and drugs, and the grave public interest in every aspect of their handling, it may be that the 12 jurors were willing to rely on the "good sense of prosecutors." Their decision can be interpreted as a simple statement that the safe distribution of drugs is more important in everyday life than keeping intact abstract elements of criminal legal theory. The layman is, of course, more alert to the value of the former; the lawyer, to the value of the latter. Whether the jury was right or wrong, it now appears that Congress will have to act before a contrary result is reached.

This case spells out a clear warning to the corner druggist: Watch how your store is operating. If you have the authority of management, the responsibility of proper management is also yours. Notice has now been served that your peers will require that you exercise your authority. **[The End]**

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[19] Cited at footnote 2, at p. 285.

By W. E. BAIER and C. W. WILSON

Proposed Basis for of Insecticide Residues

DURING more than 25 years, on various occasions, technical workers of the California Fruit Growers Exchange have struggled with the problem of safeguarding against insecticide-residue hazards, alleged or real. The experience has encompassed preparation for market and interstate shipment of both fresh citrus fruit and citrus products of various types. The following proposal is the outgrowth of that experience. Its purpose is identical with that of the Food and Drug Administration in its constant endeavor to safeguard the health of the consuming public in matters related to the use of insecticides in food production.

At first thought it would appear to the advantage of both producer and consumer if no tolerances for insecticide residues were permitted and that, if necessary for compliance with such a provision or lack of it, the use of insecticides would be abandoned. Two factors decisively mitigate against the disuse of insecticides. First, no method is yet known economically to grow crops year after year without insecticides. Without them the production goes down, together with the quality of the crop, with the result that the consumer must pay higher prices for mediocre value. This quality deterioration may be the direct effect of contamination of insects or insect fragments in the fresh produce or processed material, or it may result from the impaired health of the tree or plant. Second, safe use of insecticides is possible. The insecticide is usually applied to obtain the optimum contact with the insect pest with the least penetration or dissemination otherwise.

Tolerances In Food Products

The Authors, Members of the Research Department, California Fruit Growers Exchange, Present a Proposal So Simple, They Feel, as to Aid Everyone Concerned to Know Exactly What to Expect, Thus Removing Any Tendency of a Processor to Laxity in Residue Removal. Their Article Is Reprinted from *Food Technology* (January, 1951)

Further, insecticides, although certainly poisonous to the pests which they are designed to kill, exhibit some lower limit related to the body weight of living organisms below which no toxic effect whatever can be demonstrated—that is, a given insecticide or poison in a certain weight per unit weight of the living organism will be toxic whereas that same insecticide at some greatly reduced level of weight per unit weight of the same living organism becomes completely nontoxic. As a matter of fact, a great many poisons in extremely small amounts are actually beneficial or even essential to higher living organisms.

This tonic effect to the living organism is, of course, not the reason for insecticide tolerances. The purpose of tolerances is simply to provide a practical safeguard so that consumers, in pursuing their normal eating habits day by day, will not be subjected to amounts of insecticide residues even approaching a toxic level. Further, such tolerances should not only offer protection in normal use, but also against occasional misuse or overindulgence of particular foods, at least so far as the effects of insecticide residues may be concerned.

Approaching Determination of Tolerance

If the exact eating habits of each individual could be known, hypothetically correct tolerances might be prescribed for that individual's food supplies as they differ from those of other individuals. But this is absurd, and it is perfectly obvious that the Nation's food supply as a whole for all the Nation's consumers must be considered so far as possible in determining tolerances. The average condition must be the one which prevails in such determinations but, of course, with ample factor of safety to protect the old and weak, as well as the young and strong.

As necessary as water is to the maintenance of life, no animals—not even aquatic ones—can decrease their necessary food intake to an extreme merely by filling up with water. Conversely, if all foods which are consumed were completely dehydrated, a person could not eat as much weight of these dehydrated foods as he does of the same foods in the fresh state. The reason is that the food value largely is contained in the dry matter and, in the long run, just so much dry matter and no more or no less is required in the diet.[1] It is granted that the food value expressed in calories will vary a little between carbohydrate and protein and still more between either of these and fats or fatty oils. The point is that the addition or subtraction of water does not alter the situation providing the same amount and kind of dry matter is consumed.

From a consideration of the foregoing and other factors, the basing of tolerances on the fresh weight or "as is" weight of food is not as logical, if logic only were to be considered, as would be any one of several other bases. For example, a different tolerance for each different kind and form of food or food product might be established; the tolerance might be based on the total solids; it might be based on the calorie value; on the nonvolatile matter; or on the nonaqueous matter. We will not attempt to discuss the relative merits of each of these. Careful consideration of all of them, however, points to the last one as being the most meritorious, namely a tolerance of so many parts by weight of the insecticide residue per unit part by weight of the nonaqueous matter. A simple combination of this principle with the present method of expressing tolerance will be described in the following. First, however, the difficulties inherent with the present system of expressing tolerance will be described.

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[1] "Consumption of Food in the United States, 1909-1948," United States Department of Agriculture Miscellaneous Bulletin 691, August 1949.

Difficulties with Present Method of Expressing Tolerance

The examples taken to illustrate the shortcomings of the present method are hypothetical, but similar actual cases exist. Assume that a tolerance of a particular insecticide has been established for the fresh produce at seven parts per million (ppm). It might be five or ten or 100 for our example, but seven is taken as a likely sounding figure. By implication or definite interpretation the same seven ppm is considered to apply to various products or by-products derived from this or other commodities, in addition to applying to the fresh produce itself. In all cases the tolerance is based on "as is" weight of the particular product, whether it be fresh, liquid, dry or in some other form. The seven ppm will have been determined as the best possible tolerance so expressed in view of the toxicological studies made, the practicability of the removal of the insecticide from the fresh produce, and its tenacity in various processing procedures. The seven ppm then represents the best obtainable single tolerance consistent with safety and practical considerations for all types of food products without necessarily being specifically best adapted to any one of these products.

If the product on which this seven ppm tolerance has been established is a fruit suitable for the production of pectin, this product might be manufactured and sold, provided its content of the insecticide did not exceed seven ppm. Some insecticides and other toxic substances are very tenaciously held by pectin, this being one reason for its value as a detoxicating agent as, for example, in treatment of diarrhea.[2] The dry, powdered pectin, as produced, might then exceed the tolerance. In such case, under the present system, it is only necessary to dissolve it in water to form the well-known liquid pectin, which product would easily pass the seven ppm tolerance even though the dry pectin had been as high as 50 to 100 ppm. Yet in the use of the pectin, exactly the same amount of the dry material must be used in either case so that the same amount of the insecticide residue would be contributed to the final article of food. The amount is small in any case,[3] but if there is a reasonable way to avoid it, why should there be this discrepancy or discrimination?

[1] I. A. Manville, E. M. Bradway and A. S. McMinis, "Pectin as a Detoxication Mechanism," 3 *American Journal of Digestive Diseases and Nutrition*, 570 (1936); I. A. Manville, F. J. Reithel, P. M. Yamada, T. W. Spencer and J. R. Richardson, "Studies on Detoxication. I. Ability of Apple and Its Constituents to Counteract Toxic Effects of Lead and Arsenic, 22 *Journal of Industrial Hygiene and Toxicology* 36 (1940).

[2] Medicinally, the maximum dosage of pectin by mouth is about 10 grams.

Certain insecticide residues are quite soluble in the essential oils —for example, in oil of orange. If the seven-ppm tolerance were greatly exceeded in the oil, all that would be necessary to make a marketable product well under the tolerance would be to cut the oil to derive a household extract or a flavoring emulsion. Only a few

TABLE

Hypothetical Case of a Tolerance for an Insecticide

Citrus Food	*Nonaqueous Matter, %*	*Calories, per g.*
Single-strength citrus juice	12.4	0.50
Oil-free 65° Brix concentrate (regular process)	64.5	2.58
Essential oil	100.0	n.d.[2]
Dried meal	88.2	3.53
Seed oil	100.0	9.00
"As is" dry pectin	92.5	3.70
5.5-grade liquid pectin	3.0	0.12
Fresh grated peel	25.0[1]	0.92
Vinegar	6.0	n.d.[2]
Wine	8.0	0.32

[1] The figures in this column are equivalent to a nonaqueous matter tolerance of 50 ppm. If, in the example considered, the tolerance were expressed on the present basis, each entry in this column would have been 7.0 ppm.

[2] n.d. = Not determined.

[3] The extent to which insecticide residues in feeds carry into those animal products used for food will, of course, depend upon the properties of a specific insecticide, hence cannot be covered in a hypothetical consideration such as

drops [4] of the oil will suffice to flavor a food composition where a teaspoon of the extract might be required; this ease of measurement and better dispersion of the extract over the oil are the advantages of the extract form of flavor to the housewife but perhaps not so desirable to the larger user. The final result as to insecticide residue entering the finished food composition is the same, so why should one of these procedures be held legal and the other not?

The cutting of vinegar to make a product of lower acid strength might be considered as another example. The dilution of a fruit juice to make an ade or the dilution of concentrated juices to make either

[4] Even in medicinal use, the maximum dosage of oil is 0.3 ml.

natural-strength juice or ades may be still others. All these dilution operations have their very definite place in the distribution to consumers of very desirable and convenient forms of foods and beverages but it seems very unwise that such a dilution operation should permit the production of a food satisfactory for interstate commerce from one

Residue of 50 ppm Based on "Nonaqueous Matter"

Maximum Amount of Insecticide Residue			
"As is" basis, ppm [3]	Mg. per calorie	Mg. per serving (estimated)	
6.2	0.012	(10 oz. = 300 g.)	1.80
32.3	0.012		1.80
50.0	n.d.[2]	(U. S. Disp. dose 0.3 ml. maximum)	0.01
44.1	0.012	Not offered as human food [2]	
50.0	0.006	(20 g. on salad)	1.00
46.3	0.012	(2 oz. gel or jelly containing 1%)	0.03
1.5	0.012		0.03
12.5	0.014	(⅙ oz. per pie, 1 cut)	0.01
3.0 [4]	n.d.[2]	(4 g. on salad)	0.01
4.0 [4]	0.012	(8 oz. = 240 g.)	1.00

this table. However, the same principle applies to feeds as to foods; it is the nonaqueous matter which is the determining factor and which should therefore become the basis of the tolerance.

[4] Equivalent to 50 ppm nonaqueous matter. By combination with present tolerance basing as described in the text, this figure would be 5.0.

[5] Including 2 per cent oil.

which was not. It would seem that either both forms are satisfactory or both should be condemned, depending only upon whether the insecticide residue contributed to the finished food is satisfactorily low.

Dehydrated foods may be first diluted or reconstituted with water before consumption, or they may be eaten directly, but the dehydrated food is a concentrated food, and therefore the actual "as is" weight consumed in the long run will be proportionately less than the fresh foods. The same is true of nonaqueous materials, such as fats and oils which are highly concentrated and high in calorie value, and therefore the amounts which can be consumed are less than those of fresh

fruits and vegetables. As we have seen, the essential oils are used in extremely small quantities for another reason: to impart the required flavor. Pectin is used in small quantity to impart gel structure. The amounts of all these food products which will enter the diet are in a sense predetermined. The amounts of nonaqueous matter consumed will be essentially constant; at least these amounts will not be altered materially by adding or subtracting moisture. Therefore, it would seem that the addition or subtraction of moisture should not be a factor which determines whether a food will or will not pass an insecticide-residue tolerance.

Should producers of highly concentrated or dehydrated foods, beverage bases, condiments, flavors and food adjuncts be obliged to continue to meet a tolerance much more stringent than that for fresh fruits and vegetables, there would, in time, develop a consumer recognition of this. The idea would prevail that such concentrated foods would be safer to use than fresh produce. This is unavoidable under the present method, yet it is highly undesirable. All classes of food must be safe and, as far as possible, there should not be implied different degrees of safety. The proposed scheme attempts to accomplish the desired goal.

Proposed Basis for Expressing Tolerances

Let us now assume that a new insecticide, having shown promise from the standpoint of economic entomology, is ready for consideration of tolerance. Supported by chemical and pharmacological data, the toxicity is to be determined at various residual levels in or on the fresh fruit or vegetable to which it had been applied under practical conditions of pest control. So far as possible the fruit or vegetable selected for the major study should be a variety which is capable of growing in widely separated areas and one which is readily acceptable as a substantial part of the diet of small experimental animals. The safe upper limit or tolerance, let us assume, is found to be seven ppm, and let us further assume that the average nonaqueous matter in the produce in question is 14 per cent. The tolerance then would be expressed on the basis of nonaqueous matter, that is, it would be expressed as 50 ppm of nonaqueous matter. This is obtained by dividing seven by 14 and multiplying by 100 to give 50 ppm nonaqueous matter.

It is proposed that some figure for the fresh produce less than this seven ppm, say five ppm, be set as a nominal tolerance. Any food which passes this tolerance would be acceptable without further consideration no matter what the nonaqueous-matter content. Should this nominal tolerance of five ppm on the fresh-weight basis be exceeded, then the nonaqueous matter would be determined. If the 50 ppm nonaqueous-matter tolerance is not exceeded, the produce or product could enter into interstate commerce.

The provision for some nominal tolerance for high moisture containing fresh produce (in this case five ppm) is suggested as a method of expediting enforcement; fresh produce obviously well below the safe level could be passed with the minimum analytical procedure. In any event, the additional analyses are not difficult in view of the now generally available laboratory comminuting devices and methods of direct titration of water content.

The table above gives the relationships between the present and the proposed methods of expressing tolerances, assuming maximum allowable residues, in each product, of the same hypothetical insecticide used in the above examples. The various products listed could conceivably be made from citrus fruit. Any one particular insecticide would not distribute itself as to reach the tolerance in all these products, however. In this respect the table is hypothetical, serving to illustrate the proposed basis if the maximum permissible residues under its provisions were encountered.

The principle of this proposal is simple both as to concept and enforcement details. This simplicity would aid everyone concerned to know exactly what to expect and so remove any tendency of a processor, were he so minded, to laxity in insecticidal-residue removal. It would go a long way toward ending the pleas for special consideration of special foodstuffs. It promises to have the added legal advantage of putting broad classifications of foods under regulations that are worded the same and mean fundamentally the same thing whether considered from the point of view of the producer, processor, consumer or law-enforcement agency. **[The End]**

By ROY S. PRUITT

CHEMICAL ADDITIVES

THE subject "Chemical Additives to Food" is a broad one with several interesting and important facets. The addition of chemicals to foods is not a new practice. In fact, foods themselves are chemicals or mixtures of chemicals, and the production and processing of foods in part involve chemical processes. Complex chemical processes are involved in the digestion, metabolism and utilization of food in the body. For a long time chemicals have been added to foods to provide flavor or improve appearance or for purposes of preservation. Smoking of meats, which adds chemicals, is an example. Salt and sugar, which are chemicals, have been used in home canning for many generations. More recently, chemicals in the form of vitamins have been added to staple foods for enrichment purposes and to improve their nutritive qualities.

The first important addition of an essential nutrient to a staple article of food in this country occurred about 30 years ago, when small quantities of iodine were added to salt. It had been well established that insufficient intake of iodine was the cause of simple goiter in large areas of the United States. It had also been established that the addition of very small quantities of iodine to food would prevent simple goiter. At the present time more than half of the table salt sold in this country contains added potassium iodide, and the occurrence of simple goiter has been markedly reduced. This is a good example of a desirable chemical additive to food and it illustrates what can be done in the improvement of health when a widespread deficiency in the diet is recognized and competent methods worked out by scientists are taken to remedy it.

Since the discovery of vitamins and the vast information developed concerning their role in nutrition, the public has become "vitamin conscious" through popularization of these discoveries in books,

TO FOOD

FDA's Chief of St. Louis District Read This Paper at a Short Course on Food and Nutrition Sponsored by the College of Agriculture, University of Missouri, October 30, 1953. He Notes That, as the Law Now Stands, an Ingredient of Questionable Safety Can Be Used Until Standards Can Be Formulated and Made Effective or Until Sufficient Evidence Is Available to Establish That It Is Poisonous or Deleterious . . . .

periodicals and lectures. The Food and Drug Administration has had to deal with innumerable proposals to add vitamins and minerals to foods and beverages of all types. Too often, the sponsors of such additions are more concerned with the possible sales appeal of added magic ingredients than with the actual benefits to the users of the food. Many proposed additions are useless and unnecessary; some involve vitamins that would be quickly destroyed in the proposed mixtures. Too often, the advances in science have been prostituted, for instance, through extravagant and unwarranted promotion of vitamin preparations to prevent and cure the various ills of mankind.

However, there are a number of examples of the utilization of this relatively new scientific knowledge to improve the nutritional qualities of certain staple foods by overcoming specific dietary deficiencies. Some examples are the addition of Vitamin D to milk to prevent the development of rickets in infants, the addition of vitamins and minerals to flour and bread, and the addition of Vitamin A to oleomargarine. Vitamin D is necessary for the proper deposition of minerals in bones and if it is not available, the bones become soft and deformed. Surveys in the early 1920's showed that up to 75 per cent of the babies in our large eastern cities had rickets to some degree. At the present time this disease has practically disappeared. The universal practice of adding Vitamin D to evaporated milk which is widely used as food for infants that are not breast fed and the widespread practice of fortifying fluid milk with Vitamin D undoubtedly have played an important part in the disappearance of rickets.

The Federal Food, Drug, and Cosmetic Act authorizes the establishment of standards of identity for foods whenever in the judgment

of the Secretary such standards will promote honesty and fair dealing in the interest of consumers. When hearings were held in 1940 for the purpose of establishing a standard for flour, a considerable number of proposals to fortify flour with vitamins and minerals were advanced by the industry. As a result of the evidence adduced at that hearing, a standard was established for "enriched flour" which required the addition of specified amounts of thiamine, riboflavin, niacin and iron. Calcium and Vitamin D were made optional ingredients because the testimony indicated that there was insufficient clinical evidence of deficiency of Vitamin D and calcium to justify making them required ingredients.

Principles Which FDA Considers Essential to Promote Honesty and Fair Dealing

In authorizing or requiring the addition of chemicals of this sort to a standardized food there are certain principles which the Food and Drug Administration considers are essential to insure that such a standard will in fact promote honesty and fair dealing in the interest of consumers. These principles can be stated in this way: If a vitamin or mineral is to be added to flour, there should be evidence of deficiency of the nutrient in a substantial segment of the population. Such evidence could be obtained from surveys of the composition of dietaries used or actual occurrence of deficiency diseases. The quantity of such a nutrient added should be sufficient to make an important contribution to nutrition, but should not be in excess of what may actually be needed. A vitamin which is destroyed in large measure either through storage or in the process of preparation of the food for consumption, such as by cooking, should not be added. A vitamin should not be added if its need in human nutrition has not been established.

Subsequently, when hearings were held to consider standards for bread, it was logical to conclude that a product called "enriched bread" should have the composition that would result if enriched flour were the only cereal used in the manufacture of such bread. The bread standards as finally promulgated provide for such a product. Similarly, standards for enriched macaroni and enriched corn products have been established, and enrichment of these products follows the same pattern of providing for the addition of thiamine, riboflavin, niacin and iron, with calcium and Vitamin D as optional ingredients.

When the standard for oleomargarine was under consideration, there was no evidence of Vitamin A deficiency in important segments of our population. However, it was a fact that butter contributed a substantial part of the Vitamin A intake for our population. It also was known that Vitamin A deficiency occurred in young children in Denmark during World War I, when butter was replaced by oleomargarine. Therefore it seemed advisable to provide a standard for oleomargarine to which Vitamin A could be added. Hence the standard requires that if oleomargarine is represented to contain Vitamin A, it must contain not less than 15,000 units per pound, which is the average Vitamin A content of butter.

The establishment of standards for enriched flour and enriched bread does not mean that all flours and breads are enriched, but only that products represented as enriched flour or enriched bread must conform with the standards. However, 26 states have enacted laws prohibiting the sale in those states of flour or bread that has not been enriched. Five southern states also have passed laws making it compulsory to enrich corn products in accordance with the federal standards. Undoubtedly these actions have substantially contributed to the disappearance of pellagra and riboflavin deficiencies which were widespread in some of our southern states a couple of decades ago, and they undoubtedly have contributed to improved nutrition elsewhere.

National Research Council's Food and Nutrition Board

We have in this country a sound guiding influence for bringing about nutritional improvement of our foods in the Food and Nutrition Board of the National Research Council. This council has established committees of outstanding scientists to advise governmental agencies on problems of a scientific nature. In 1941, at the request of the Commissioner of Food and Drugs, the Food and Nutrition Board provided a statement of policy, with respect to the addition of vitamins and minerals to foods, which represents the best statement of the philosophy of food fortification that we have. It has been very helpful to the Administration in considering many problems involving proposed food fortification.

Other facets of this subject of chemical additives to food involve additions that are not nutritionally desirable, that may be harmful or that may result in debasing a food from the nutritional standpoint.

I should like to discuss briefly some of the aspects of this phase of the subject.

The Federal Food, Drug, and Cosmetic Act prohibits the shipment in interstate commerce of food products that are adulterated. There are several types of adulteration defined by the law. A food that bears or contains any poisonous or deleterious substance which may render it injurious to health is adulterated. A food which bears or contains any added poisonous or added deleterious substance which is not required in the production of the food or which can be avoided by good manufacturing practice is adulterated. But when such a substance is required or cannot be avoided, the law provides a means for the promulgation of safe tolerances.

Government's Burden of Proof

Food law enforcement officials are confronted with a serious problem and consumers are subjected to possible hazards when substances are added to foods, either accidentally or deliberately, for which there is inadequate information concerning toxicity. This results from the fact that when the government proposes to take action against a food to which an allegedly poisonous or deleterious substance has been added, the government must be prepared to prove that the substance is poisonous or deleterious and is not necessary in the production of the food. In a case involving fluorine in beer the courts ruled that the amount present is irrelevant. That was a recognized poison, but many substances are still under investigation.

Chemical additives in food may represent residues of pesticides employed to prevent insect devastation of agricultural crops during the growing period, or to protect such crops or foods manufactured therefrom from insect infestation during storage. Other chemical additives may represent substances that have been deliberately added to manufactured foods for the purpose of fancied or real improvement. Various emulsifiers and softeners are examples.

"Spray Residue" Project

The use of pesticides is necessary in the production of many agricultural crops. Pesticide residues remaining on food crops may be the source of contamination. Consequently, the "spray residue"

project for a long time has been an important activity of food officials —the investigation and analysis of samples to insure that the food products do not contain harmful amounts of residues. Metallic poisons, such as lead arsenate and sodium fluoride, have been used to spray orchards for many years. These substances are known poisons for which methods of analysis are available. When residues are present they can be detected and measured and, under existing law, the consuming public can be protected.

During and following World War II numerous new organic insecticides have been developed. The first and probably best-known of the chlorinated hydrocarbons is DDT. This substance became available for general use shortly after the war, and has come into widespread use on a variety of agricultural crops. Studies show that this material is absorbed and is stored in the body in the fatty tissues, and that if an animal is exposed to it for a long time or ingests small amounts over a period of time, it may accumulate in the fat in amounts that will definitely be injurious. It is essential then that residues on food products be kept below amounts that can possibly be harmful.

Many other chlorinated hydrocarbons and other organic insecticides have been developed and put into use. Little is known about the toxicity of many of them. Some quickly evaporate and leave no residues, but others may be absorbed by plants or break down into other chemical compounds that may leave residues as toxic as the parent substance. The identity and toxicity of many such decomposition products are unknown. Methods of detection and analysis of many of these new compounds or their decomposition products are likewise not known yet.

New Chemicals

The rapid advances in science during the past decade also have resulted in the development and production of a whole host of new chemicals, some of which have been advocated and promoted for use in food products to accomplish alleged improvements. A number of such substances, when incorporated in the shortening used in bakery products, are said to produce more tender products. Among these are the so-called bread softeners. Emulsifiers have been suggested for use as dispersing agents in flavors, essential oils, in polyvitamin solutions to maintain uniform mixtures, and for use in ice cream to produce a smoother product.

The advent of this host of new organic chemicals for use as pesticides and insecticides that may come into contact with foods, and the growing use of food additives—such as softeners and emulsifiers—have served to direct attention to a serious gap in the consumer protection afforded by the Federal Food, Drug, and Cosmetic Act. The present law, which was enacted in 1938, requires premarketing tests of new drugs to ensure their safety when used as directed. The law does not make any comparable requirement for the testing of new food additives before they are used. While the authority to prescribe food standards may be exercised and has been exercised in certain instances to exclude additives whose safety is suspect, the prescribing of standards for each food is a slow process, and is not a practicable or effective solution of the problem. As the law now stands, an ingredient of questionable safety can be used in food until such time as standards can be formulated and made effective or until sufficient evidence is available to establish that it is poisonous or deleterious. This may take many years, during which time the public may be consuming the food and playing the role of guinea pigs.

House Bills Submitted

Congress has been alert to the potential hazards of this situation. In June, 1950, the Select Committee to Investigate the Use of Chemicals in Food Products was established by the House of Representatives. This has been known as the Delaney Committee, as Congressman Delaney was the chairman. The committee held extensive hearings throughout the country and has acquired a mass of information from scientists and authorities in various fields. It concluded that the increasing use of chemical additives in the production, processing, preservation and packaging of food has created a serious public-health problem, and it recommended that the Federal Food, Drug, and Cosmetic Act be amended to require that chemicals employed in or on foods be subjected to substantially the same safety requirements as now exist for new drugs. Bills have been introduced by Congressman Delaney and Congressman Miller dealing with certain aspects of this problem, and active consideration of the proposed legislation can be anticipated. **[The End]**

Judicial, Administrative and Legislative Developments

Significant Comments

By THOMAS W. CHRISTOPHER

Inspection

Searches and Seizures.—The question of searches and seizures under the the Fourth Amendment [1] has vexed the Supreme Court in unusual fashion for the past eight or nine years, and some of the reversals and seeming reversals by the Court have left lawyers in a state of uncertainty. Because of their search-and-seizure aspects, two recent food and drug decisions by a district court will be of interest to the legal profession in general.

In the first case, *U. S. v. Arnold's Pharmacy, Inc.*,[2] the court held that where the operator of a pharmacy voluntarily allowed inspectors to search his records, evidence found could be used in a criminal proceeding under the Food and Drug Act. In the second case, *U. S. v. Scientific Aids Company*,[3] the court reached a similar conclusion, even though it stated that the defendant acquiesced "perhaps reluctantly."

An essential element of these holdings is the finding that the search was permissive, that is, that the defendant allowed the inspectors to look through the records. If the operator of the store had consented as a result of fear or of intimidation, on the other hand, the search would have been illegal, and the evidence would have been suppressed.[4]

[1] "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated . . . ."

[2] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7269, 116 F. Supp. 310 (N. J., 1953).

[3] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7274 (N. J., 1954).

[4] *Davis v. U. S.*, 328 U. S. 582 (1946).

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This leads one to speculate about how much persuasion an inspector may use regarding permission to inspect records without bringing the search into conflict with the Fourth Amendment. To put the two extremes, to ask permission would not of itself violate the amendment; to demand at the point of a gun clearly would. But suppose the inspector threatens to get a search warrant or to prosecute the owner or to inspect his store every day for six months? Again, may the inspector go a step beyond the mere request and attempt to persuade by logic based on a good citizen's duty to cooperate with the government? These are serious questions for the FDA and industry to consider, especially in view of the restrictive interpretation the factory-inspection amendment is receiving.

Section 703.—These two cases also deal with the scope of the "exempt from prosecution" clause of Section 703 of the Act,[5] both courts holding that Section 703 does not apply where access is voluntarily given. In the *Arnold's Pharmacy* decision, the court writes:

> Thus since, under well settled principles, those who voluntarily turn over their records to the Government cannot object to their use in criminal proceedings, it can hardly be claimed that this statutory amendment was intended to prevent such use under such circumstances. On the other hand, it is clear both from the purpose of the amendment and its terms, that the section was intended to apply where access to the records was refused the Government.

[5] Sec. 703: ". . . carriers . . . and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee . . . permit such officer . . . at reasonable times, to have access to . . . records . . . ; and it shall be unlawful . . . to fail to permit such access . . . when such request is accompanied by a statement in writing . . . ; *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained . . . "

It is thus apparent that one must refuse permission to see the records in order to come under Section 703. The two decisions are especially interesting due to the fact that they appear to be the first two *criminal* cases directly dealing with this clause of the section.

Permission To Inspect.—Section 704, prior to the factory-inspection amendment, granted permission to inspect "after first making request and obtaining permission of the owner, operator or custodian." In *Golden Grain Macaroni Company v. U. S.*,[6] the Ninth Circuit had occasion to consider the meaning of the word "custodian" in the quoted passage. In this case, the president and general manager of the corporation was absent from the state when the inspectors presented themselves. They asked who had authority to give them permission to inspect and were informed by the receptionist that the company's sales manager so had. When asked, said sales manager granted permission for the inspection. The court, in upholding the inspection, writes: ". . . [the sales manager] was held out to the officers as the person in charge, and he acted as such. The authority of the Administrator to make investigations of this nature is broadly granted."

The decision would appear to be in line with the underlying purpose of the Act, since by any other construction an owner or operator could defeat inspection merely by staying away from the plant. It will be remembered that in the *Maryland Baking Company* case [7] the manager was on the premises but in conference, and the inspectors obtained permission from the plant superintendent.

The new factory-inspection amendment alters Section 704 in this regard to read "upon presenting appropriate credentials and a written notice to the owner, operator, or *agent in charge* . . . ." (Italics supplied.) Without doubt there is at least some difference between the meanings of the words "custodian" and "agent," and one can only speculate on how this case would be decided under existing law. The committee reports on the factory-inspection amendment both state that the intention in using "agent" is to refer "to a person at the establishment or vehicle who is a responsible representative of management." The House report adds that it was thought that "custodian" might be held "to mean a mere caretaker." [8]

[6] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7273 (CCA-9, 1953).

[7] *U. S. v. Maryland Baking Company*, 81 F. Supp. 560 (DC Ga., 1948).

[8] H. R. Rept. No. 708, 83d Cong., 1st Sess. (1953), p. 11; S. Rept. No. 712, 83d Cong., 1st Sess. (1953), p. 6.

Removal

An unusual situation under the removal provisions of Section 304(a) [9] arises in *U. S. v. 353 Cases . . . Mountain Valley Mineral Water.*[10] This section provides for the removal of actions "to any district agreed upon by stipulation between the parties" or, if there is no stipulation, the court may on motion remove to "a district of reasonable proximity to the claimant's principal place of business . . . ." This indicates that an action may be removed to *any* district by stipulation, but that if the government opposes, a district of "reasonable proximity" must be selected. Cases have held that "reasonable proximity" excludes the district in which the claimant's principal place of business is located.[11]

In the *Mountain Valley* case, the claimant on motion in the original or first court removed to a district adjacent to the district of its home office. The second court, on stipulation of both parties, then sent the case to the home district of the claimant. But the third or home-district court holds on its own motion that the second court could not send the case over to the home district even on stipulation. This is based on the reasoning that the first court could not have so done (on motion, although it could have on stipulation), and that the second court had no power not given the first, that in fact the only authority of the second court was to try the case. The third court further holds, and this is the heart of the holding, that the "statute authorizes only one application" for removal, and that application must be to the court in which the seizure has been made (whether upon stipulation or motion). Thus, only the original court has power to transfer.

Taking the language of Section 304(a) at face value, this ruling is sound where the removal to the third court is by motion, but a reasonable argument can be made against the rule when the removal to the third court (or second and third) is by stipulation. The statute reads that:

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[9] Sec. 304(a): "In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial."

[10] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7271, 117 F. Supp. 110 (DC Ark., 1953).

[11] *U. S. v. 23 Gross Jars . . . Enca Cream,* 86 F. Supp. 824 (DC Ohio, 1949).

. . . the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties . . . .

The language which follows, dealing with removal by motion, reads that *"the claimant may apply to the court of the district in which the seizure has been made . . . ."* Thus, the portion on removal by motion states clearly that the first or original court is the only place, while the portion on stipulations says nothing in this regard. There is dictum in the decision upon which the *Mountain Valley* decision mainly rests to the effect that one can stipulate from the second to a third court:

> The power of removal is exclusively conferred under the act upon the court of original jurisdiction, barring of course the existence of a stipulation of the parties on the subject.[12]

Drugs

Cigarettes.—Some time ago the Federal Trade Commission brought forward the contention that cigarettes, under certain conditions, are "drugs" within the meaning of that term as defined in the Federal Trade Commission Act. A New York district court rejected this contention.[13] It held that mere listing of the name "tobacco" in one of the official compendiums did not of itself make the item a drug,[14] and that the actual entry under "tobacco" in the compendium in question made clear that all tobacco was not considered to be a drug. The court went on to find that claims in advertising that a particular cigarette prevents irritation are not enough to classify the item as a drug.

In a more recent case,[15] a federal district court has ruled that, under certain conditions, cigarettes may be drugs within the scope of the Food and Drug Act.[16] In this case the cigarettes were accompanied by leaflets depicting their beneficial effect in reducing the frequency of certain respiratory diseases. The leaflets were entitled, "How . . . Cigarettes may help you." The court says:

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[12] *U. S. v. Six Dozen Bottles . . . "Dr. Peter's Kuriko,"* 55 F. Supp. 458 (DC Wis., 1944).

[13] *FTC v. Liggett & Myers Tobacco Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7245, CCH TRADE REGULATION REPORTS ¶ 67,377, 108 F. Supp. 573 (DC N. Y., 1952), aff'd, CCH TRADE REGULATION REPORTS ¶ 67,486, 203 F. (2d) 955 (CA-2, 1953).

[14] See *Ohio v. Winterich*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 85,133, 157 Ohio St. 414, 105 N. E. (2d) 857 (1952).

[15] *U. S. v. 46 Cartons . . . Cigarettes . . .*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7263, 113 F. Supp. 336 (N. J., 1953).

[16] The definition of "drugs" in Sec. 15(c) of the Federal Trade Commission Act is exactly the same as in Sec. 201(g) of the Food and Drug Act.

The clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections. This is enough to bring the product within the statutory meaning of "drug."

The principle involved in this decision is beyond question, namely, that any product may be a drug if the producer or seller holds it out as such. The only contest concerns the effect of the facts. Thus, do these facts add up to a drug?

In an early case, mineral water was held to be a drug because it was sold as a treatment for Bright's disease.[17] In like manner, plain air could be a drug if it were sold as a treatment for a disease. The only problems arise because the technical statute is helpless in the shadow areas between food and drugs. Technically, why isn't iodized salt a drug? Or whiskey? What about prune juice? It is sold as a food but many people buy it for its laxative values and, in fact, physicians often suggest its use. As with so much of law, the solution here lies in having wise administrators of the law, for courts can be saved many hard decisions by administrators with the good sense not to bring unimportant cases in this shadow area.

Coming back to the two cigarette decisions, it seems clear that they are not in conflict but rather differ on the facts.

Proprietary Medicines.—A New Jersey superior court has ruled that a regulation by the state board of pharmacy saying that only pharmacists may vend "patent" or "proprietary" medicines is unreasonable on the ground that the regulation does not reasonably promote health, safety or welfare.[18] This decision is in line with decisions of several other states.[19] As a general rule, where the court sees a statute as having no purpose other than to give a monopoly on the sale of patent and proprietary medicines, it will strike it down.

State Cases

Injunction.—An Alabama case [20] deals with an unusual problem—injunctions in criminal matters. A statute authorizes state inspectors to inspect fruits and vegetables when packed in closed packages, and also any place where such products are so packaged, stored or sold.[21]

[17] *Bradley v. U. S.*, 261 F. 79 (CCA-5, 1920).

[18] *The Proprietary Association v. . . . Board of Pharmacy*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 85,139 (Super. Ct. of N. J., Essex Co., July 20, 1953).

[19] *State v. Donaldson*, 41 Minn. 74 (1889) (accord); *State v. Child*, 32 Ariz. 222 (1927) (accord); *State of Wisconsin v. Wakeen*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 85,137, 263 Wis. 401, 57 N. W. (2d) 364 (1953) (contra).

[20] *Corte v. State of Alabama*, 67 So. (2d) 782 (Ala. Sup. Ct., 1953).

[21] Alabama Code, Title 2, Secs. 315(9)-(16) (Supp., 1951).

Violation is a misdemeanor. The Alabama Supreme Court upheld an injunction requiring a producer-seller to permit inspection.

The principle of law involved is a respectable one, although courts have not often used it. As one court said:

> The power of equity to enjoin the doing of acts threatening irreparable injury to property rights or which would constitute a public nuisance is inherent and has been exercised, both in England and America, by courts of chancery . . . , nor can this power be devested because the performance of such acts may be a violation of the criminal law.[22]

Res Ipsa Loquitur.—A recent exploding-bottle case, *Morrison v. Kansas City Coca-Cola Bottling Company*,[23] discusses in some detail an important aspect of the doctrine of *res ipsa loquitur*, namely, the effect of proof by the defendant that he has complied with customary usage and methods in the industry. The court held that such proof is evidence of lack of negligence, but is not conclusive.

The general rule in negligence cases is that conformance to custom or usage is a proper matter to be submitted to the jury, but is not a test which is conclusive or controlling.[24] Custom or usage may be evidence of what ought to be done, but it is only evidence; what ought to be done, in the final analysis, is determined by the standard of the ordinarily prudent man. This rule has some exceptions, as for example in suits against storekeepers for injuries due to falls in the building,[25] but is generally applied in food and drug cases.[26]

Imitation.—A recent Kansas decision [27] deals with a variation of the problems in imitations and in filled milk, in connection with statutes regulating "ice milk." A statute defines "ice milk" as:

> . . . a frozen product . . . made in semblance of ice cream, but containing less than ten per cent (10%) milk fat. Ice milk shall not contain any fats, oils . . . other than the milk fat . . . .

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[22] *State v. Woolfolk*, 269 Mo. 389, 190 S. W. 877, 878 (1916). See also *People v. Monterey Fish Products Company*, 195 Cal. 548, 234 Pac. 398 (1925); *Farmers Co-Operative Association v. Quaker Oats Company*, CCH TRADE REGULATION REPORTS (Supp., 1941-1943) ¶ 52,905, 233 Ia. 701, 7 N. W. (2d) 906 (1943); *Clark v. Crown Drug Company*, 348 Mo. 91, 152 S. W. (2d) 145 (1941); *State v. Allen*, 180 Miss. 659, 177 So. 763 (1938).

[23] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,342, 263 Pac. (2d) 217 (Kan., 1953).

[24] *Grant v. Graham Chero-Cola Bottling Company*, 176 N. C. 256, 97 S. E. 27 (1918); *Cadillac Motor Car Company v. Johnson*, 221 F. 801 (CCA-2, 1915); *Shannahan v. Empire . . . Corporation*, 204 N. Y. 543, 98 N. E. 9 (1912). *See* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 20,551; 68 A. L. R. 1400 (1930).

[25] *Chilberg v. Standard Furniture Company*, 63 Wash. 414, 115 Pac. 837 (1911).

[26] *Canada Dry Ginger Ale Company v. Jochum*, 43 Atl. (2d) 42 (D. C., 1945); *Honea v. Coca Cola Bottling Company*, 143 Tex. 272, 183 S. W. (2d) 968 (1944). *Contra: Ketterer v. Armour & Company*, 247 F. 921 (CCA-2, 1917) (meat).

[27] *Dairy Belle, Inc. v. Freeland*, 264 Pac. (2d) 894 (Kan., 1953).

The statute then prohibits the sale of "ice milk" which does not conform to this definition.

The product involved in this case is sold as as "soya frozen dessert," and it contains no milk fat, but does contain 11 per cent of soybean fat.

The court holds that the product is in "semblance" of ice cream and that, since it contains less than 10 per cent butterfat, it cannot be sold if it contains vegetable oil. The constitutionality is upheld on the ground that the legislature has the power to protect the public from fraud, and also under the due process clauses of the federal and state constitutions.

The decision appears to be in accord with the statute inasmuch as the latter says plainly that "ice milk" shall not contain fats other than milk fats. On the constitutional questions, the decision is in line with many holdings on filled-milk statutes. The interesting question here is whether or not the producer could have sold the product under the name "imitation ice milk." On the surface, at least, it would seem that he could not, the reason being that the imitation provision is in the state food and drug law, and he is accused of violating the state filled-dairy-products law, two separate statutes.

• FOOD—PRICE-FIXING, UNFAIR COMPETITION •

Tomatoes . . . Under the terms of a recent initial decision, partial dismissal of a complaint charging 24 tomato-processing companies with combining to boycott and destroy a cooperative association of tomato growers has been ordered. The complaint alleged that the processors, by agreement, refused to buy raw tomatoes from members of a co-operative. It also charged that the processors collusively fixed the prices they pay the growers. Charges to the effect that certain individuals combined to boycott the cooperative and to destroy its tomato markets are not dismissed. (Initial order released February 20, 1954.)

Ice cream . . . Eight major ice cream manufacturers and 55 of their subsidiaries operating nation-wide are charged with unfair methods of competition in the sale of ice cream and related frozen products. Complaints allege that respondents offer unfair inducements in seeking accounts—in the form of cash loans, bonus payments, discriminatory discounts, and refrigeration equipment made available on terms and conditions calculated to make each dealer an exclusive seller of their products. The complaints charge that these practices injure the smaller ice cream manufacturer with limited capital and that, if continued, they would result in further concentration of the ice cream manufacturing business in the hands of a few major companies. (Complaints issued February 15, 1954; released March 1, 1954.)—CCH TRADE REGULATION REPORTS ¶ 11,628; 11,633.

" . . for all concerned with doing business in Canada."

CANADA'S FOOD *and* DRUG LAWS

by ROBERT E. CURRAN, Q. C.
Legal Adviser to Canada's Department
of National Health and Welfare

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A Word About the Institute . . .

The Food Law Institute, Inc., was organized for constructive development of the food law, including the related drug and cosmetic laws, by a number of leading food manufacturers in 1949, and is principally supported by them. It is ably headed by Charles Wesley Dunn, a foremost authority on food, drug, and cosmetic law. A major aim of the Institute is to prepare basic research studies of the food law by authorities in the field—published by Commerce Clearing House, Inc., leading publisher of Topical Law Reports and publications on federal food and drug law. The series of books is known as the FOOD LAW INSTITUTE SERIES.

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